### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

		FORM 20-	F
	REGISTRATION STATEMENT PURSO OF 1934	UANT TO SECTION	12(b) OR (g) OF THE SECURITIES EXCHANGE ACT
		OR	
X	ANNUAL REPORT PURSUANT TO S For the fiscal year ended December 31,		I) OF THE SECURITIES EXCHANGE ACT OF 1934
		OR	
	TRANSITION REPORT PURSUANT T For the transition period from	O SECTION 13 OR to	15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
		OR	
	SHELL COMPANY REPORT PURSUA 1934	ANT TO SECTION 1	3 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
Date of	event requiring this shell company report	t <b>:</b>	
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		Genmab A/ Kalvebod Bryg 1560 Copenhag Denmark Tel: +45 7020 Fax: +45 7020	hief Financial Officer S ge 43 gen V 2728
Securiti	ies registered or to be registered pursuant to S	Section 12(b) of the A	ct.
	Title of each class	Trading symbol	Name of each exchange on which registered
Ameri	can Depositary Shares, each representing one-tenth of one ordinary share	GMAB	The NASDAQ Stock Market LLC
Ordina	ry shares, nominal value DKK 1 per share	GMAB	The NASDAQ Stock Market LLC*
* Not fo	or trading, but only in connection with the re	gistration of the Amer	ican Depositary Shares on The NASDAQ Stock Market LLC.

Securities registered or to be registered pursuant to Section 12(g) of the Act. None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

by the annual report.						
		65,545,748 Ordina	ry Shares (including shares	s underlying American Dep	ositary Shares)	
				47,953,970 American De	positary Shares	
Indicate by check mark	if the registrar	nt is a well-known seasone	ed issuer, as defined in Rule	405 of the Securities Act. Yes	s 🗆 No 🛛	
-		report, indicate by check ct of 1934. Yes □ No <b>∑</b>	mark if the registrant is not r	equired to file reports pursua	nt to Section 13	
Exchange Act of 1934 d	luring the prec	• • •	eports required to be filed by uch shorter period that the re 90 days.	` '		
		0	ctronically every Interactive for for such shorter period tha	•		
•			nted filer, an accelerated filer, schange Act. (Check one):	, or a non-accelerated filer. S	ee definition of	
Large accelerated fi	ler 🛮	Accelerated filer $\square$	Non-accelerated filer $\square$	Emerging growth c	ompany $\square$	
If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards <sup>†</sup> provided pursuant to Section 13(a) of the Exchange Act. $\square$						
† The term new or revised financial accounting standard refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.						
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.						
Indicate by check mark	which basis o	f accounting the registrant	has used to prepare the finar	ncial statements included in t	his filing:	
□ US GAAP	<b>☒</b> Internation	1 0	tandards as issued by the Int andards Board	ernational Accounting	☐ Other	
If "Other" has been check has elected to follow $\Box$	-	• •	n, indicate by check mark wh	nich financial statement item	the registrant	
If this is an annual Exchange Act). Yes $\Box$	•	e by check mark whether	the registrant is a shell comp	any (as defined in Rule 12b-	2 of the	

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#### INTRODUCTION

In this Annual Report on Form 20-F the terms the "Company", "Genmab", "we", "us", "our" and the "Group" refer to the parent company Genmab A/S together with its consolidated subsidiaries. The term "Genmab A/S" is used when addressing issues specifically related to this legal entity.

Pursuant to Rule 12b-23 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we incorporate information for certain items of this Annual Report on Form 20-F by reference to certain pages of the Genmab A/S statutory Annual Report 2020 (the "Annual Report 2020"), included as Exhibit 99.1(a) to Form 6-K furnished to the U.S. Securities and Exchange Commission (the "SEC") on February 23, 2021. Therefore, the information in this Annual Report on Form 20-F should be read in conjunction with the Annual Report 2020. Items not contained or not specifically referenced to within the Annual Report 2020 should not be deemed to be part of this Annual Report on Form 20-F.

#### FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding sales and net sales, clinical development, regulatory approvals and commercialization of daratumumab, ofatumumab and teprotumumab by Janssen Biotech, Inc ("Janssen"), Novartis International AG ("Novartis") and Horizon Therapeutics plc ("Horizon"), respectively;
- our expectations regarding the clinical development, regulatory approval and commercialization of tisotumab vedotin and our other proprietary and partnered product candidates;
- our expectations with regard to our ability to create and develop additional product candidates and to submit investigational new drug ("IND") applications and/or clinical trial applications ("CTAs") for our pre-clinical product candidates;
- our receipt of future milestone payments and royalties from our partners, and the expected timing of such payments;
- our estimates and expectations regarding the potential market size and the size of the patient populations for our products and product candidates;
- our expectations regarding the potential advantages of our products and product candidates over existing therapies or therapies currently in development;
- our expectations regarding the potential advantages of our proprietary technologies over existing antibody technologies and the prospects for our ongoing and future technology collaborations;
- our plans to expand our translational research platform and the potential benefits of such platform;

- our expectations with regard to the willingness and ability of our current and future partners to
  pursue the development, approval and commercialization of our products and product candidates;
- our and our partners' product discovery, development and commercialization plans with respect to our products and product candidates and our proprietary technologies;
- our potential to enter into new collaborations;
- our and our partners' ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals for our products and product candidates;
- our ability to identify, and to negotiate contracts with, suitable contract manufacturing organizations
  ("CMOs") and the ability of such CMOs to manufacture sufficient quantities of our products and
  product candidates for clinical trials or commercialization in compliance with current good
  manufacturing practices ("cGMPs") (as defined herein);
- the commercialization and market acceptance of our products and product candidates;
- our plans to build our commercialization capabilities and to potentially commercialize tisotumab vedotin or other proprietary product candidates in-house;
- the pricing of and reimbursement for our approved products;
- the implementation of our business model and strategic plans for our business, products, product candidates and technologies;
- our ability to operate our business without violating applicable laws and regulations;
- our and our partners' ability to operate our businesses without infringing the intellectual property rights and proprietary technology of third parties;
- the scope of protection we and our partners are able to establish and maintain for intellectual property rights covering our products, product candidates and technologies;
- our analysis of potential patent infringement claims and our or our partners' rights with respect to such claims;
- estimates of our future expenses and revenue;
- our expectations regarding regulatory developments in the United States, the European Union, Japan and other jurisdictions;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain suitably qualified employees and key personnel, particularly for our commercialization efforts;

- our future financial performance; and
- developments and projections relating to our competitors and our industry, including competing therapies and technologies.

The forward-looking statements contained herein involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements.

You should understand that many important factors, in addition to those discussed or incorporated by reference in this report, could cause our results to differ materially from those expressed in the forward-looking statements. Potential factors that could affect our results include, in addition to others not described in this report, those described under "Item 3.D—Risk Factors." These are factors that we think could cause our actual results to differ materially from expected results.

Forward looking statements speak only as of the date on which they are made, and we undertake no obligation to update any forward-looking statements or other information contained in this report, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we make in our reports on Form 6-K furnished or filed with the SEC. Please also see the cautionary discussion of risks and uncertainties under "Item 3.D—Risk Factors." This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995

#### PRESENTATION OF FINANCIAL AND OTHER INFORMATION

We maintain our books and records in Danish kroner and report under International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). None of the audited consolidated financial statements (the "Audited Financial Statements") included in our Annual Report 2020 and incorporated by reference into this Annual Report on Form 20-F were prepared in accordance with accounting principles generally accepted in the United States. We use the symbol "\$" to refer to the U.S. dollar, "DKK" to refer to the Danish kroner and the symbol "€" to refer to the Euro herein. While our financial results disclosed herein are presented in Danish kroner, certain amounts paid or payable to or by us under certain of our collaborations are presented in the currencies in which payments under such collaborations are denominated.

All references to "shares" in this Annual Report on Form 20-F refer to ordinary shares of Genmab A/S with a nominal value of DKK 1 per share.

This Annual Report on Form 20-F includes trademarks, tradenames and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks, tradenames and service marks referred to in this Annual Report appear without the @,  $^{\text{TM}}$  and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks, tradenames and service marks to the fullest extent under applicable law. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

This Annual Report on Form 20-F contains estimates, projections and other information concerning our industry, our business and the markets for our products and product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Item 3. D —Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Forward-Looking Statements" above.

### **ENFORCEABILITY OF CIVIL LIABILITIES**

We are organized under the laws of Denmark, with a domicile in the municipality of Copenhagen, Denmark.

A majority of the members of our board of directors and senior management are residents of Denmark or other jurisdictions outside the United States. A substantial portion of ours and such persons' assets are located in Denmark or other jurisdictions outside the United States. As a result, it may not be possible for investors to effect service of process upon such persons or us with respect to litigation that may arise under U.S. law or to enforce against them or our company judgments obtained in U.S. courts, whether or not such judgments were made pursuant to civil liability provisions of the federal or state securities laws of the United States or any other laws of the United States.

The United States and Denmark do not have a treaty providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, a final judgment (other than an arbitration award) rendered by a U.S. court based on civil liability would not be enforceable in Denmark. However, if the party in whose favor such final judgment is rendered brings the lawsuit in a competent court in Denmark, that party may submit to the Danish court the final judgment that has been rendered in the United States. A judgment by a federal or state court in the United States against the Company will neither be recognized nor enforced by a Danish court, but such judgment may serve as evidence in a similar action in a Danish court.

#### PART I

### ITEM 1 IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

#### ITEM 2 OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

### ITEM 3 KEY INFORMATION

**B.** Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

#### D. Risk Factors

#### Risks Related to Our Business

Our financial results and near-term prospects are substantially dependent on DARZALEX. If our partner Janssen is unable to effectively maintain and grow sales of DARZALEX for its approved indications and to continue to expand its indications, our prospects for increased revenues and profitability will be adversely affected.

In 2020, royalties and milestone payments from Janssen related to daratumumab, marketed as DARZALEX for certain indications of multiple myeloma ("MM"), accounted for 45% of our revenue, as compared to 92% in 2019, and we anticipate that DARZALEX will continue to account for a substantial portion of our revenue in the near term. The decrease was mainly driven by the upfront payment of \$672 million (DKK 4,398 million) related to the AbbVie collaboration that was allocated to license grants and recognized as revenue in June 2020. Excluding the one-time payment from AbbVie, royalties and milestone payments from Janssen related to daratumumab, marketed as DARZALEX for certain indications of MM, accounted for 79% of our revenue. Under our collaboration agreement regarding daratumumab, Janssen is currently fully responsible for developing and commercializing daratumumab and all costs associated therewith. Consequently, our revenue and resulting operating profit, if any, and near-term prospects are substantially dependent on the success of this collaboration and on Janssen's continued ability to effectively maintain and grow sales of daratumumab for its approved indications and to continue to expand its indications. Janssen has obtained marketing approval for DARZALEX for certain indications of frontline MM and relapsed/refractory, ("R/R"), MM in the United States, the European Union, Japan and in certain other countries. In addition, Janssen obtained marketing approval for the subcutaneous ("SubQ") formulation of daratumumab (daratumumab and hyaluronidase-fihj) in the U.S., where it is known as DARZALEX FASPRO, and in Europe, where it is known as DARZALEX SC. The SubQ formulation of daratumumab has also been approved in Japan. In the U.S. Janssen also obtained marketing approval for DARZALEX FASPRO for the treatment of light-chain ("AL") amyloidosis. Regulatory applications are currently pending with U.S. and European authorities based on the APOLLO study and with European and Japanese authorities based on the ANDROMEDA study. There can be no assurance that Janssen will be successful in obtaining additional approvals for DARZALEX or jurisdictions or in maintaining existing regulatory approvals. The FDA approval based on the ANDROMEDA study was granted as an accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). While DARZALEX product sales have grown over time, and our future plans assume that sales of DARZALEX will continue to increase, there can be no assurance that, even with the recent expansion to the prescribing label for DARZALEX in the United States and the European Union, DARZALEX sales will continue to grow or that Janssen will be able to maintain sales of DARZALEX at or near current levels. In particular, DARZALEX is subject to intense competition in the MM therapy market. There are numerous other products approved by the U.S. Food and Drug Administration (the "FDA") for the same indications as DARZALEX and the competition from these and other therapies is intensifying. We are also aware of numerous additional investigational agents and technologies that are currently being studied for the treatment of MM, any of which may compete with DARZALEX in the future. In particular, Sanofi's isatuximab, a monoclonal antibody ("mAb") targeting CD38, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor ("PI"). If Janssen is unable to successfully compete with these other agents and technologies, DARZALEX sales could decline materially.

Janssen is also currently conducting clinical trials of daratumumab for the treatment of smoldering MM, ("SMM"), and additional indications of frontline MM and R/R MM, as well as certain other diseases in which CD38 is expressed, including AL amyloidosis, for which Janssen submitted a Biologics License Application ("BLA") to the FDA in September 2020, based on the Phase III ANDROMEDA study. This BLA was subsequently approved by the FDA in January 2021.

Although we are able to participate in the development strategy for daratumumab through regular meetings of the joint development and steering committee, we cannot control the amount and timing of resources that Janssen dedicates to the development and commercialization of daratumumab and our prospects for future milestone payments and royalties related to daratumumab depend on Janssen's decision to continue to conduct clinical trials of daratumumab for

expanded indications and to seek new regulatory approvals for daratumumab, and on the success of such studies and applications and to its active commercialization.

There can be no assurance that Janssen will complete the ongoing and planned studies of daratumumab, successfully or at all, or that Janssen will obtain and maintain the regulatory approvals necessary to market daratumumab for any additional indications. In particular, despite the FDA label expansion of daratumumab based on the ANDROMEDA study, there can be no assurance that additional marketing authorizations will be granted based on the ANDROMEDA study, that marketing approval will be granted based on the APOLLO study, that any of the other studies will be completed on the expected timeline or at all, or, if completed, that the final results of such studies will be positive. Negative or inconclusive results in these or other trials would negatively impact, or preclude altogether, Janssen's ability to obtain regulatory approvals for daratumumab in the proposed indications, which would limit the commercial potential of daratumumab. For example, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with atezolizumab for the treatment of patients with previously treated non-small-cell lung cancer, ("NSCLC"), was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus atezolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in this arm of the study. Based on these findings, a Phase I study of daratumumab and Janssen's proprietary anti-PD-1 antibody for the treatment of patients with MM was also discontinued. Even if the results of Janssen's ongoing studies are positive, there can be no assurance that Janssen will apply for regulatory approval of the related indications and, if Janssen applies, that such applications will be successful, each of which would limit the commercial potential of daratumumab. Additionally, even if Janssen receives the required regulatory approvals to market daratumumab for any additional indications or in additional jurisdictions, Janssen may not be able to effectively commercialize daratumumab as a result of unfavorable pricing or reimbursement limitations, competition or other factors, or may choose not to prioritize daratumumab in its commercialization efforts.

In addition, the royalties payable by Janssen are limited in time and subject to reduction on a country-by-country basis for customary reduction events, including upon patent expiration or invalidation in the relevant country and upon the first commercial sale of a biosimilar product in the relevant country (for as long as the biosimilar product remains for sale in that country). Pursuant to the terms of the agreement, Janssen's obligation to pay royalties under this agreement will expire on a country-by-country basis on the later of the date that is 13 years after the first sale of daratumumab in such country or upon the expiration of the last-to-expire relevant product patent (as defined in the agreement) covering daratumumab in such country. Our issued U.S., European and Japanese patents covering the composition of matter for daratumumab do not begin to expire until March 2026.

In September 2020, Genmab commenced binding arbitration of two matters arising under the license agreement with Janssen relating to daratumumab. The arbitration is to settle whether Genmab is required to share in Janssen's royalty payments to Halozyme Therapeutics, Inc. ("Halozyme") for the Halozyme enzyme technology used in the SubQ formulation of daratumumab and whether Janssen's obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-to-expire relevant Janssen-owned patent covering daratumumab. See "Item 8—Financial Information—Legal Proceedings".

Future prospects for daratumumab are also subject to the risks outlined below with respect to our other product candidates, including risks related to clinical studies, adverse events, regulatory requirements and approvals, intellectual property matters, competition, manufacturing, pricing, reimbursement and marketing. In addition, future prospects for daratumumab are also subject to the risk that we will be unable to successfully manage our relationship with Janssen as outlined below.

Our future prospects for ofatumumab are dependent on our partner Novartis' ability to successfully expand ofatumumab's indications and to effectively commercialize it for its current indications and any new indications that may be approved, as well as on other external factors that could impact ofatumumab's future success.

A SubQ formulation of ofatumumab has been approved for the treatment of certain relapsing forms of multiple sclerosis ("RMS") indications in the United States under the name Kesimpta. Under our collaboration agreement,

Novartis is fully responsible for development and commercialization of ofatumumab and all costs associated therewith. Consequently, the commercial success of ofatumumab is dependent on the success of this collaboration and the activities of Novartis. We cannot control the amount and timing of resources that Novartis dedicates to the development and commercialization of ofatumumab and our ability to obtain royalties related to ofatumumab depends on Novartis' decision to continue to study ofatumumab for new indications, to seek regulatory approvals for such indications and to effectively commercialize ofatumumab for new and existing indications, and on the success of such efforts. Kesimpta is also subject to competition in the RMS therapy market. There are numerous other products approved by the FDA for RMS, in particular Genentech's ocrelizumab, a mAb targeting CD20, which was approved as Ocrevus. Ocrevus was initially approved by the FDA in 2017 for relapsing or primary progressive forms of multiple sclerosis ("MS"). The current FDA approved indications for Ocrevus are RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults as well as primary progressive MS in adults. If Novartis is unable to successfully compete with this and other therapies, Kesimpta sales could be materially affected.

On January 22, 2018, Novartis announced that it would transition Arzerra in non-U.S. markets from commercial availability to limited availability through managed access programs or alternative solutions, where applicable and allowed by local regulations, due to increased availability of other treatments for chronic lymphocytic leukemia ("CLL") resulting in a low number of patients using Arzerra outside the United States. In 2019, marketing authorizations for Arzerra were withdrawn in the European Union and certain other territories. Subsequently, in August 2020 Genmab announced that Novartis planned to transition Arzerra to an oncology access program for CLL patients in the U.S. Genmab recognized \$30 million lump sum from Novartis as payment for lost potential royalties. Ofatumumab is no longer in development for CLL. We expect Arzerra to remain commercially available for approved CLL indications in Japan.

Our future prospects for teprotumumab are dependent on Horizon's ability to successfully expand teprotumumab's indications and to effectively commercialize it for its current indications and any new indications that may be approved, as well as on other external factors that could impact teprotumumab's future success.

Teprotumumab has been approved for the treatment of thyroid eye disease ("**TED**") in the United States under the name TEPEZZA. The antibody was created by Genmab under a collaboration with Roche and development and commercialization of the product is now being conducted by Horizon under a license from Roche. Under the terms of Genmab's agreement with Roche, Genmab will receive mid-single digit royalties on net sales of TEPEZZA. Horizon is fully responsible for development and commercialization of teprotumumab and all costs associated therewith. Consequently, the commercial success of teprotumumab is dependent on the success of the activities of Horizon. We cannot control the amount and timing of resources that Horizon dedicates to the development and commercialization of teprotumumab and our ability to obtain royalties related to teprotumumab depends on Horizon's decision to continue to study teprotumumab for new indications, to seek regulatory approvals for such indications and to effectively commercialize teprotumumab for new and existing indications, and on the success of such efforts.

Biopharmaceutical product development involves a substantial degree of uncertainty. Our current product candidates are in various stages of development, and it is possible that none of our product candidates will become viable commercial products, on a timely basis or at all.

Our clinical stage product candidates include eight proprietary product candidates, ongoing clinical studies for daratumumab, ofatumumab and teprotumumab by Janssen, Novartis and Horizon, respectively, and twelve additional product candidates being developed in collaboration with our partners. We also have approximately 20 proprietary and partnered product candidates in pre-clinical development. Other than amivantamab, in development by Janssen, tisotumab vedotin and epcoritamab, which are all currently in Phase III development, our current product candidates are in relatively early stages of development. All of our product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all.

Due to the uncertain, time-consuming and costly clinical development and regulatory approval process, we or our partners may not successfully develop any of our product candidates, or we or our partners may choose to discontinue the development of product candidates for a variety of reasons, including due to safety, risk versus benefit profile,

exclusivity, competitive landscape, commercialization potential, production limitations or prioritization of our or our partners' resources. It is possible that none of our current product candidates will ever obtain regulatory approval and, even if approved, such product candidates may never be effectively commercialized. In addition, our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates suitable for clinical development or commercialization. Likewise, we and our partners have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance. We may not have the resources to invest in all of our current product candidates, or clinical data and other development considerations may not support the advancement of one or more product candidates.

Decision-making about which product candidates to prioritize involves inherent uncertainty, and our and our partners' development program decision-making and resource prioritization decisions may not improve our results of operations or future growth prospects or enhance the value of the American depositary shares ("ADSs").

Additionally, our most advanced proprietary product candidate, tisotumab vedotin, is currently in Phase III development with a BLA submitted in January 2021, and we have not advanced any product candidates through late-stage clinical development ourselves. If we are unable to develop late-stage development capabilities, we will be required to continue to contract with third parties to complete the development of our proprietary product candidates, which we may not be able to do on a timely basis, on terms favorable to us or at all, and the development of our proprietary product candidates could be delayed or terminated. Our failure to effectively advance our development programs could have a material adverse effect on our business, financial condition, results of operations and future growth prospects, and cause the market price of our ADSs to decline.

We have no history of commercializing our marketed products. Building our commercialization capabilities will require significant investment of time and money. There can be no assurance that we will successfully set up our commercialization capabilities, or that we will successfully commercialize any of our product candidates in the future.

We are currently building and expanding our commercialization capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create value for our customers and shareholders. Our goal is to become a commercial-stage company with an initial focus on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seagen Inc. ("Seagen"). In October 2020, we and Seagen entered into a joint commercialization agreement. Genmab will co-promote tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. In all other markets, if any, Seagen will be responsible for commercializing tisotumab vedotin and Genmab will receive royalties based on a percentage of aggregate net sales ranging from the mid-teens to the mid-twenties. The companies will continue the practice of joint decision-making on the worldwide development and commercialization strategy for tisotumab vedotin. Furthermore, in June 2020, we entered into a collaboration and license agreement with AbbVie Biotechnology Ltd. ("AbbVie"), pursuant to which we intend to jointly research, develop, manufacture and commercialize certain product candidates. The development of our commercialization capabilities will benefit from the experience gained with AbbVie's infrastructure, procedures and commercialization best practices in connection with this collaboration.

Our market based commercialization operations are currently being developed. Building comprehensive commercialization capabilities will require substantial investment of time and money and will require significant management focus and resources. We will be competing with larger pharmaceutical and biotechnology companies with established commercialization and marketing capabilities. In addition, we may be unable to develop productive relationships with local medical experts, patients and other key stakeholders or may face barriers due to cultural or regulatory differences. We will also compete for staffing with transnational and local pharmaceutical and biotechnology firms and local medical, healthcare and research organizations. Accordingly, there can be no assurance that our efforts to set up commercialization capabilities will be successful.

Even if tisotumab vedotin or one of our other proprietary product candidates obtain regulatory approval, we may determine that commercializing such product candidate ourselves would not be the most effective way to create value for our shareholders. In addition, if we choose to commercialize any of our product candidates, our marketing efforts may be unsuccessful as a result of unfavorable pricing or reimbursement limitations, delays, competition or other factors. Failure to successfully market one or more of our approved products, or delays in our commercialization efforts, may diminish the commercial prospects for such products and may result in financial losses or damage to our reputation, each of which may have a negative impact on the market price of our ADSs and our financial condition, results of operations and future growth prospects.

Tisotumab vedotin may not obtain regulatory approval, on our expected timeline or at all, and, if it is approved, we may be unable to effectively commercialize it. We do not have sole control over the development and commercialization of tisotumab vedotin.

Tisotumab vedotin is currently our most advanced proprietary product candidate, and our initial commercialization efforts are focused on setting up our commercialization capabilities to market tisotumab vedotin for the treatment of cervical cancer. We are developing tisotumab vedotin in collaboration with Seagen under an agreement in which the companies share all future costs and profits for the product on a 50:50 basis. Under our agreement, Seagen and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. However, there can be no assurance that tisotumab vedotin will obtain regulatory approval on our expected timeline or at all. We and Seagen conducted a potentially registrational Phase II clinical trial of tisotumab vedotin for the treatment of patients with recurrent and/or metastatic cervical cancer and reported very favorable topline results for this study in June 2020. A confirmatory Phase III study was subsequently announced in January 2021. There can be no assurance that the Phase III study will be completed, on the proposed timeline or at all, or that the results will be supportive of the Phase II clinical trial. A BLA submission was made to support a potential accelerated approval pathway with the U.S. FDA. There is no guarantee that we will obtain marketing approval or, if we obtain marketing approval, that we and Seagen will be able to successfully commercialize tisotumab vedotin. If we are unable to commercialize tisotumab vedotin for cervical cancer, we may lose a portion of our investment and may incur additional costs to refocus our efforts on other products or indications, which could have a negative impact on our business, financial condition, results of operations and future growth prospects.

In October 2020, we and Seagen entered into a joint commercialization agreement. Genmab will co-promote tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. In all other markets, if any, Seagen will be responsible for commercializing tisotumab vedotin and Genmab will receive royalties based on a percentage of aggregate net sales ranging from the mid-teens to the mid-twenties. The companies will continue the practice of joint decision-making on the worldwide development and commercialization strategy for tisotumab vedotin. If we and Seagen are unable to continue to agree on the development and commercialization strategies for tisotumab vedotin, such efforts may be delayed, or we may be required to take full responsibility for ongoing development and commercialization efforts, including the costs of such efforts. In addition, either party may opt out of co-development and profit-sharing in return for receiving milestone payments and royalties from the continuing party.

Furthermore, tisotumab vedotin is developed using Seagen's proprietary antibody-drug conjugate ("ADC") technology in combination with our proprietary HuMax-TF antibody. Any failures or setbacks in Seagen's ADC development programs, including adverse effects resulting from the use of ADC technology in commercial settings or human clinical trials and/or the imposition of clinical holds on any trials for product candidates using this technology, could have a detrimental impact on the continued development of tisotumab vedotin, which could adversely affect our business, financial condition, results of operations and future growth prospects.

Our research & development efforts may not succeed in generating a continued pipeline of products. Any failures or setbacks in our DuoBody platform or our other proprietary technologies could negatively affect our business and financial condition.

Discovering and developing new products is a costly and uncertain process. Substantial resources are required in order to yield innovations. It is important for us to pursue early stage research and development in order to ensure a sustained portfolio of products.

This is in part driven by the productivity of our proprietary technologies. Many of our proprietary and partnered product candidates are created with, and dependent upon, our proprietary technologies, including our proprietary epcoritamab (DuoBody-CD3xCD20), DuoBody-CD40x4-1BB and DuoBody-PD-L1x4-1BB product candidates, which were created with our DuoBody technology, as well as several additional product candidates in clinical development by Janssen through our DuoBody collaboration, including amivantamab, our proprietary HexaBody-DR5/DR5 and HexaBody-CD38 product candidates, which were created with our HexaBody technology, and our proprietary DuoHexaBody-CD37 product candidate, which was created with our DuoHexaBody technology. Our DuoBody technology is also the basis of our collaborations with certain other partners, including Novo Nordisk and BioNTech and our HexaBody technology is the basis of our CD38 collaboration with Janssen. To date, no products based on any of these technologies have been approved for commercial sale in any jurisdiction. Any failures or setbacks with respect to our proprietary technologies, including adverse effects resulting from the use of these technologies in human clinical trials and/or the imposition of clinical holds on trials of any product candidates using our proprietary technologies, could have a detrimental impact on our clinical pipeline, as well as our ability to maintain and/or enter into new corporate collaborations regarding our technologies or otherwise, which would negatively affect our business and financial condition.

### Several of our products and product candidates are used or proposed to be used in combination with other therapeutic products, which exposes us to risks related to those products.

Part of the clinical development strategy for certain of our product candidates, including daratumumab, is to seek to identify patients or patient subsets within a disease category whose treatment may benefit from our products in combination with other therapeutic products. For example, daratumumab has been approved in certain jurisdictions in combination with other products, including with (i) lenalidomide and dexamethasone ("Rd"), for the frontline treatment of transplant-ineligible MM patients and for the treatment of MM patients who have received at least one prior line of therapy; (ii) bortezomib and dexamethasone, ("Vd"), for the treatment of MM patients who have received at least one prior line of therapy; (iii) pomalidomide and dexamethasone, ("Pd"), for the treatment of MM patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor, ("PI"); (iv) bortezomib, melphalan and prednisone ("VMP"), for frontline treatment of transplant-ineligible MM patients; (v) bortezomib, thalidomide and dexamethasone ("VTd"), for frontline treatment of transplant-eligible MM; (vi) carfilzomib and dexamethasone ("Kd"), for the treatment of adult patients with relapsed/refractory MM who have received one to three previous lines of therapy and (vii) in combination with bortezomib, cyclophosphamide and dexamethasone ("VCd"), for the treatment of AL amyloidosis. In addition, daratumumab is currently under regulatory review in combination with other products, including (i) Pd, for the treatment of MM patients who have received at least two prior therapies, including lenalidomide and a PI and (ii) in Europe, in combination with VCd, for the treatment of AL amyloidosis. Daratumumab is also in Phase III clinical trials with (i) bortezomib, lenalidomide and dexamethasone ("VRd") and VMP for frontline treatment of transplantineligible MM patients; and (ii) VRd and lenalidomide for frontline treatment of transplant-eligible MM patients. We and our partners are also testing other product candidates as combination treatments.

Approval of a product for the treatment of a disease indication in combination with other therapeutic products exposes us and our partners to certain risks related to those other therapeutic products, including the risks that such products will become less competitive or obsolete or will be found to have safety concerns, which could potentially result in removal of such products from the market. For example, in May 2012, the FDA issued a safety announcement relating to the risk of second primary malignancies in patients with newly diagnosed MM that had received lenalidomide, marketed as Revlimid, and on July 18, 2013, Celgene, in consultation with the FDA, discontinued treatment with Revlimid in a Phase III trial for the treatment of previously untreated elderly patients with CLL due to an

imbalance observed in the number of deaths in patients treated with Revlimid versus patients treated with chlorambucil. Furthermore, seeking to heighten immune or other therapeutic responses through combination treatments carries an inherent risk that the combination may cause unexpected side effects or safety issues not observed in treatment with the individual products alone. For example, in May 2019, Regeneron Pharmaceuticals Inc. reported that the combination of its bispecific mAb with a PD-1 inhibitor led to enhanced cytokine release syndrome in patients in a Phase I trial and was a potential cause of two patient fatalities in the study. In addition, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with atezolizumab in patients with previously treated NSCLC was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus atezolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in the combination treatment arm of the study.

## Partnerships are an important part of our strategy and we may not be able to continue our current partnerships or establish additional partnerships.

We have entered into a number of different partnerships for development, co-development, commercialization and cocommercialization of our products and product candidates, as well as for the in- and out-licensing of third-party technologies and our proprietary technologies. Our ability to continue our current partnerships and to enter into additional partnerships will depend in large part on whether we are able to successfully demonstrate our ability to select and develop product candidates and whether our antibody technology and other platform technologies are attractive formats for developing antibody therapeutic products. Existing or potential partners may pursue alternative technologies, including those of our competitors, or enter into other transactions that could make collaboration with us less attractive to them. For example, if an existing partner purchases or is purchased by one of our competitors, that company could be less willing to continue its collaboration with us. Moreover, from time to time we have discussions, disagreements or disputes with our partners with respect to the ownership of rights, royalty entitlements or other matters with respect to any technology or products developed with our partners or with respect to the interpretation of related agreements. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays in or termination of the research, development or commercialization of products and product candidates or affect the financial and non-financial rights and obligations under the related agreements. If we are not able to establish additional partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely limit the number of product candidates that we would be able to develop and commercialize, significantly increase our need for capital and/or place additional strain on management's time, any of which could materially harm our business, financial condition and results of operations. Furthermore, as discussed above, we cannot assure you that we would be able to establish the necessary internal product development and commercialization capabilities to develop and commercialize our product candidates ourselves in a timely matter or at all, or that any product development or commercialization activities we carry out would be successful.

We rely on our partners' willingness and ability to devote resources to the development and commercialization of our products and product candidates and to otherwise support our business as contemplated in our partnership agreements, which may be terminated.

We rely on our partners to support our business, including to assist with, or to conduct, clinical and regulatory development, manufacturing and/or commercialization of certain of our products and product candidates or to provide access to antigens, technologies, skills and information that we do not possess. For example, we have granted Janssen worldwide exclusive rights to develop and commercialize daratumumab, have granted Novartis worldwide exclusive rights to develop and commercialize ofatumumab, and have also entered into partnerships with AbbVie, Seagen and BioNTech for certain of our proprietary product candidates. In addition, we have granted Janssen and Novo Nordisk certain rights to develop product candidates using our DuoBody technology platform. We have also created product candidates that have been out-licensed to Janssen, Roche, Bristol-Myers Squibb ("BMS"), ADC Therapeutics, Lundbeck and Amgen, and have entered into a research collaboration and exclusive license agreement with Immatics Biotechnologies GmbH, or Immatics, to discover and develop potential next-generation bispecific immunotherapies to target multiple cancer indications. We have also entered a research collaboration and license agreement with CureVac AG to develop differentiated mRNA-based antibody products and an exclusive license and option agreement with

Janssen to develop a next-generation CD38 product using our HexaBody technology platform. As part of our partnership with AbbVie we will also enter into a discovery research collaboration to select and develop up to four additional differentiated next-generation antibody-based product candidates, potentially across both solid tumors and hematological malignancies. If we do not realize the contemplated benefits from our collaborations, our business, financial condition and results of operations may be materially harmed.

In particular, the termination of our key partnerships could significantly delay the development and commercialization of our products and product candidates and impact our financial results and future prospects. Our licensing partners generally have the right to terminate our partnerships with notice at any time. For example, Janssen has the right to terminate our collaboration agreement concerning daratumumab with 150 days' written notice to us, Novartis has the right to terminate the co-development and collaboration agreement concerning ofatumumab at any time by providing nine months' prior written notice to us, and Seagen has the right to opt out of co-development and profit-sharing of tisotumab vedotin in return for receiving milestone payments and royalties from us. In particular, any disruption to our collaboration with Janssen or changes in Janssen's product development or business strategy for daratumumab could result in a material decline in our revenue. In addition, any failure by Janssen to perform its obligations under our agreement for any reason, including its obligations to make milestone payments or pay royalties, could have a material adverse effect on our financial performance. Our near-term prospects for product development and commercialization could also be significantly impacted by any disruption in, or termination of, our collaborations with Seagen and AbbVie for tisotumab vedotin and epcoritamab, respectively.

We also rely on our partners to periodically provide us with information about the status, progress and results of clinical trials and regulatory processes that they are conducting, sponsoring or pursuing with respect to our partnered products. We generally do not have direct access to the underlying data or direct communications with the relevant regulators. As a result, our knowledge of material clinical events or data or material regulatory communications or developments, and our corresponding ability to report these to our shareholders, may be limited or delayed.

In addition, our reliance on our partners subjects us to a number of additional risks, including the following:

- our partners have significant discretion regarding whether and on what timeline to pursue planned activities;
- we cannot control the quantity and nature of the resources our partners may devote to the development, commercialization, marketing and distribution of products or product candidates;
- our partners may not develop products generated using our antibody technology as expected;
- disputes between us and our partners may delay or terminate the research, development or commercialization
  of the applicable products and product candidates or result in costly litigation or arbitration that diverts
  management's attention and resources;
- we may not receive milestone payments from our partners, at the expected time or at all, if our partners do not achieve future milestones or if we and our partners disagree about whether a milestone has been reached;
- with respect to collaborations under which we have an active role, we and our partners may have differing
  opinions or priorities, or we may encounter challenges in joint decision making, which may delay or
  terminate the research, development or commercialization of the applicable products and product candidates;
- our partners may delay, terminate or repeat clinical trials or require a new formulation of a product candidate for clinical testing, or may abandon a product candidate;

- our relationships with our partners may divert significant time and effort of our scientific staff and management team;
- our partners may be subject to regulatory sanctions that could adversely affect the development, approval or commercialization of the applicable products or product candidates;
- our partners may not properly maintain or defend relevant intellectual property rights, or may infringe the
  intellectual property rights of third parties, or may use our or third parties' proprietary information in such a
  way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to
  potential litigation;
- our partners may develop competing products, therapeutic approaches or technologies;
- business combinations, financial difficulties or significant changes in a partner's business strategy, including
  as a result of the COVID-19 pandemic, may adversely affect that partner's willingness or ability to continue
  to pursue our products or product candidates; and
- our collaborations may be terminated, breached or allowed to expire, or our partners may reduce the scope of our agreements with them.

Any one or more of the foregoing risks, if realized, could have a material adverse effect on our business, financial condition and results of operations.

If our license agreements violate the competition provisions of the EC Treaty, then some terms of our key agreements may be unenforceable.

Certain license agreements that we have entered into, or may enter into, will grant or may grant exclusive licenses of patents, patent applications and know-how and, therefore, might be found to be restrictive of competition under Article 81(1) of the EC Treaty. Article 81(1) prohibits agreements which restrict competition within the European Community and affect trade between member states. We determine on an agreement-by-agreement basis whether an existing exemption from the application of Article 81(1) applies to the agreement. If an exemption is not applicable, provisions of any license agreement which are restrictive of competition under Article 81(1), including those relating to the exclusivity of rights, may be unenforceable and we could lose the benefit of the rights granted under the provision and may be ordered to pay fines and damages to third parties.

Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA, the EMA and any other comparable regulatory authority, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of these product candidates.

The FDA, the European Medicines Agency ("EMA") and comparable regulatory authorities in other jurisdictions must approve new product candidates before they can be marketed, promoted or sold in those territories. We or our partners must provide these regulatory authorities with data from pre-clinical studies and clinical trials that demonstrate that our product candidates are safe and effective for a specific indication before they can be approved for commercial distribution. DARZALEX, Kesimpta and TEPEZZA are our only approved products. We cannot be certain that our or our partners' clinical trials for our product candidates will be successful or that any of our other proprietary or partnered product candidates will receive approval from the FDA, the EMA or any other regulatory authority. In addition, certain other third parties make decisions about products or product candidates based on results of clinical trials, including determinations relating to pricing or reimbursement of approved products or validations or endorsements of treatment options. Such third parties may require additional data or studies for their determinations.

Pre-clinical studies and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays or failure. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years and require significant expenditures to complete the pre-clinical studies and clinical trials necessary to commercialize a product candidate, and delays or failures are inherently unpredictable and can occur at any stage. Topline or interim results of clinical trials do not necessarily predict final results, and success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials, and we cannot be certain that we or our partners will not face similar setbacks. If topline or interim data that we or our partners report differ from final results, if others, including regulatory authorities, disagree with our assumptions, calculations, conclusions, or analyses or interpret or weigh the data differently, or if subsequent studies are unsuccessful, we or our partners may be unable to obtain marketing approval for product candidates on a timely basis or at all, which could impact our reputation, business, financial condition, results of operations and future growth prospects.

The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. In addition, advancements or changes in the industry standards or techniques may impact the value and recognition of our and our partners' clinical data. Failure to adopt new industry standards may result in less comparable or useful study results. Alternately, early adoption of emerging protocols or endpoints may result in data that is not recognized by certain regulatory bodies or industry professionals, or if such protocols are later found to be ineffective, may require us or our partners to change the design of our clinical trials. For example, Janssen has selected minimal residual disease ("MRD"), an emerging efficacy endpoint in MM, as the primary endpoint in the Phase III CEPHEUS trial of daratumumab in combination with VRd for the treatment of frontline MM and in the Phase III AURIGA trial of daratumumab in combination with lenalidomide as maintenance treatment for MM patients who are MRD positive after frontline autologous stem cell transplant.

Although these trials include more conventional measures as secondary endpoints, such as progression free survival ("PFS") and overall survival ("OS"), this design may not be sufficient to obtain regulatory approval, and Janssen may be required to change the design of these trials or conduct additional trials to obtain regulatory approval for these indications. Similarly, limitations of MRD as an endpoint may result in a need for more comprehensive results. Changing the design of a clinical trial can be expensive and time-consuming. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us and may require us or our partners to delay, reduce the scope of or eliminate one or more product development programs, which could have a material adverse effect on our business, financial position, results of operations and future growth prospects. In addition, any delays in product development may allow our competitors to bring products to market before we do or shorten any periods during which we or our partners have the exclusive right to commercialize our product candidates.

In connection with clinical trials of our product candidates, we face a number of risks, including risks that:

- we or our partners may be unable to manufacture or obtain sufficient quantities of qualified materials for clinical trials or may be required to modify manufacturing processes;
- patient recruitment may be slower than expected;
- a product candidate may be ineffective, inferior to existing approved products for the same indications, unacceptably toxic or have unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- a clinical trial may be delayed, suspended or terminated by the institutional review board or ethics committee
  responsible for overseeing the clinical study, by regulatory authorities or by us or our partners due to failure
  to meet clinical protocols, safety issues or adverse effects, failure to demonstrate product

efficacy, changes in clinical protocols or applicable regulatory requirements, lack of funding or other factors;

- investigators or other third parties could conduct clinical studies on our products or product candidates that could lead to adverse events or results that could negatively impact the development, regulatory approval or marketability of such products;
- extension studies on long-term tolerance could invalidate the use of our product;
- final results of studies may not confirm positive interim results or the results of earlier trials;
- results may not meet the level of statistical significance required by the FDA, the EMA or other relevant regulatory agencies to establish the safety and efficacy of our product candidates for continued trial or marketing approval;
- even if data is sufficient for regulatory approval, it may not be sufficient to secure pricing reimbursement or
  to secure validation of our products by key industry players, which could delay or prevent the commercial
  launch of a product; and
- our partners or contract research organizations ("CROs"), may be unable or unwilling to perform under their contracts.

Furthermore, we sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical trials, the submission of regulatory filings or the achievement of commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve announced milestones in the timeframes we expect, or at all, the commercialization of our product candidates may be delayed, and we may not be entitled to receive certain contractual payments, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

Results of pre-clinical or early clinical trials may not be indicative of results obtained in later clinical trials, the timing and outcomes of which are always uncertain, and our product candidates may not successfully complete clinical trials on our expected timeline or at all.

Even if we or our partners obtain positive results from pre-clinical or early clinical trials, we or they may not achieve the same success in subsequent trials. In particular, the results of pre-clinical trials are based on animal, *in vitro* or other laboratory testing and may not be predictive of the safety or efficacy of our product candidates in humans. Similarly, the results of early stage clinical trials are based on a limited number of patients and may, upon further review, be revised or negated by regulatory authorities or by later-stage clinical results. Historically, industry-wide results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. Industry-wide, a number of new drug and biologic candidates have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including emerging knowledge or changes in regulatory policy during the period of product development.

Clinical trials may not demonstrate statistically sufficient levels of safety and efficacy to obtain the requisite regulatory approvals. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could

harm the development of the relevant product candidate as well as other product candidates employing the same technology, which could have a significant impact on our product pipeline and future growth prospects.

We rely on third parties to conduct our clinical trials and if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We do not currently have the ability to independently conduct clinical trials. With respect to our proprietary product candidates or any other product candidates for which we control the clinical development, we rely on third parties, such as CROs, to conduct clinical trials on our product candidates. For our out-licensed products and product candidates, or for any product candidates where our partner is responsible for clinical development, we rely on such partners to conduct clinical trials. These partners may also hire CROs or other third parties to conduct clinical studies on our products and product candidates. The third parties with whom we and our partners contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. The FDA and regulatory authorities in Europe and other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices ("cGCPs"), for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

Many of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to cGCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be costly, and our clinical trials may need to be extended, delayed, terminated or repeated. We may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, or to commercialize such product candidate being tested in such studies or trials.

We and our partners have conducted and intend to conduct additional clinical trials for selected products and product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations due to the study design and conduct, trial population or for other reasons, or may require additional U.S.-based trials.

We and our partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, particularly in the European Union where we are headquartered. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted by qualified investigators in accordance with cGCPs, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any clinical trials that we or our partners conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these product candidates for the proposed indications in the United States.

In other jurisdictions, for instance, in Japan, there is a similar risk regarding the acceptability of clinical trial data conducted outside of that jurisdiction. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden
  or limit our and our partners' ability to conduct clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient
  population in the target markets where approval is being sought.

### If we or our partners encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We or our partners may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving our product candidates and or related technologies;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate
  being studied in relation to other available therapies, including any new drugs or treatments that may be
  approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our and our partners' clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available for our and our partners' clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. We expect that we and our partners will conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our and our partners' clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential

patients and their doctors may be inclined to only use conventional therapies, such as chemotherapy and radiation, rather than enroll patients in any future clinical trial.

Even if we and our partners are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our and our partners' ability to advance the development of our product candidates.

### Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics, or to enter into successful commercial arrangements for such diagnostics, could harm our development strategy.

We may seek to identify patient subsets within a disease category that may derive selective and meaningful benefit from the product candidates we are developing. Through collaborations, we may develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates. Companion diagnostics are subject to regulation by the FDA, the EMA and comparable foreign regulatory authorities as companion diagnostic medical devices, and typically require separate regulatory approval prior to commercial use. We expect that we may develop companion diagnostics in collaboration with third parties and may be dependent on the scientific insights and sustained cooperation and effort of such partners in developing and obtaining approval for companion diagnostics. We and our partners may encounter difficulties in developing and obtaining approval for any companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by us or our partners to obtain regulatory approval of companion diagnostics could delay or prevent approval of our product candidates. In addition, we or our partners may encounter production difficulties that could constrain the supply of the companion diagnostics, and may experience difficulties gaining acceptance of the use of such companion diagnostics in the clinical community. Failure to gain market acceptance of such companion diagnostics could have an adverse effect on our or our partners' ability to successfully commercialize such product candidates. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we or our partners anticipate using in connection with development and commercialization of our product candidates, or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative companion diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

### We are subject to extensive and costly government regulation, and are required to obtain and maintain governmental approvals to commercialize our products.

Product candidates employing our antibody technology are subject to extensive and rigorous government regulation. The FDA, the EMA and similar regulatory agencies in other countries regulate the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. The regulatory review and approval or licensing process is lengthy, expensive and uncertain and requires the submission of extensive pre-clinical and clinical data and supporting information for each indication to establish the product candidate's safety and efficacy. We or our partners may be unable to obtain regulatory approval on the basis of such data if the relevant regulatory authorities disagree with the design or implementation of the clinical trials, determine that the results of such trials do not meet the requisite level of statistical significance, disagree with our or our partners' interpretation of such data, determine that we or our partners have not demonstrated the safety and efficacy of the product candidate or that its benefits outweigh its risks or fail to approve the manufacturing processes or facilities for the product candidate. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, particularly as we move towards the commercial stage of our product candidates, we may be required to report some of these relationships to the FDA or other regulatory authorities, as well as to certain national registers or other applicable agencies. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. We have not

obtained regulatory approval for any of our proprietary product candidates and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Even if we or our partners are able to obtain approval for our products or product candidates, regulatory authorities may grant approval for fewer or more limited indications than requested, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of such product candidate.

In addition, once a product obtains regulatory approval, numerous post-approval requirements apply, including periodic monitoring and reporting obligations, review of promotional material, reports on ongoing clinical trials and adverse events and inspections of manufacturing facilities. In addition, material changes to approved products, including any changes to the manufacturing process or labeling, require further review by the appropriate authorities before marketing. Approvals may also be withdrawn or revoked due to safety, effectiveness or potency concerns, including as a result of adverse events reported in patients or ongoing clinical trials, or failure to comply with cGMPs. In addition to revocation or withdrawal of approvals, we and our partners may be subject to warnings, fines, recalls, criminal prosecution or other sanctions if we fail to comply with regulatory requirements. If we or our partners are unable to obtain or maintain regulatory approvals for our products and product candidates, our business, financial condition, results of operations and future growth prospects will be negatively impacted and we or our partners may be subject to sanctions. In addition, even if our products are approved for marketing, we or our partners may be unable to market our products, successfully or at all, if we are unable to obtain favorable pricing for our products or if third-party payors do not agree to provide reimbursement for our products, at favorable rates or at all. See "—Risks Related to Government Regulation" below for more information about the regulatory risks we and our partners face.

Any approval granted for our products or product candidates in the United States does not assure approval of such products in the European Union or other foreign jurisdictions.

In order to market and sell our drugs in the European Union and other jurisdictions, we and our partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, many countries outside the United States require that the drug be approved for reimbursement before the drug can be approved for sale in that country. We and our partners may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

Reports of adverse or undesirable events or safety concerns involving daratumumab, ofatumumab, teprotumumab or our proprietary or partnered product candidates could delay or prevent us or our partners from obtaining or maintaining regulatory approvals, or could negatively impact sales and prospects of our products and product candidates.

As with most biological drug products, use of our products and product candidates could be associated with undesirable side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. In particular, many of our and our partners' clinical trials are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product candidates are used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our product candidates. Reports of adverse events or safety concerns could have negative impacts on our or our partners' clinical trials, regulatory processes, reputation and results.

Such adverse events or safety concerns involving our products or product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, or could negatively impact patient enrollment in, or completion of,

clinical trials. For example, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with atezolizumab in patients with previously treated NSCLC was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus atezolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in the combination arm of the study. Based on these findings, a Phase I study of daratumumab and Janssen's proprietary anti-PD-1 antibody for the treatment of patients with MM was also terminated. In addition, in June 2018, a Phase I study of JNJ-63709178, one of the product candidates being developed by Janssen through our DuoBody collaboration was put on clinical hold due to the occurrence of a Grade 3 adverse event. This hold was subsequently lifted and the study is ongoing. However, there can be no assurance that this study will not be halted again or terminated in the future. The Phase I/II clinical trial for our HexaBody-DR5/DR5 product was put on a brief partial clinical hold for discussions with the U.S. FDA around liver toxicity. After the protocol was amended with additional provisions to mitigate liver toxicity risk the partial hold was lifted in October 2019 and enrollment of patients was re-opened. The study is currently recruiting, but there can be no assurance that this study will not be halted again in the future.

In addition, reports of adverse events or safety concerns involving our products or product candidates could result in regulatory authorities limiting, denying, withdrawing approval of or recalling such product for any or all indications, including the use of such product in its previously approved indications, or may require additional clinical trials, updates to the prescribing information, including boxed warnings, contraindications, or other labeling statements, implementation of a Risk Evaluation and Mitigation Strategy ("REMS") or the issuance of field alerts, warnings or other communications to physicians, pharmacies or patients. In certain cases, regulatory authorities may order us or our partners to conduct additional trials or to cease further development or commercialization of the product or product candidate entirely.

Furthermore, actual or potential drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates. Reports of adverse events or safety concerns, or changes to regulatory approvals or labeling, may also have a significant impact on market acceptance of our products by patients and physicians or may trigger potential product liability claims, fines, injunctions or the imposition of civil or criminal penalties. Any of these events could prevent us or our partners from developing, commercializing or maintaining market acceptance of daratumumab, ofatumumab, teprotumumab or the particular product candidate or could substantially increase commercialization costs, which could significantly harm our business, financial condition, results of operations and future growth prospects.

Adverse events may also impact the sales of our products. We may be required to further update the prescribing information for our products, including boxed warnings, limitations of use, contraindications, warnings and precautions, and adverse reactions, based on reports of adverse events or safety concerns, or implement a REMS, which could adversely affect the acceptance of our products in the market, make competition easier or make it more difficult or expensive for us to distribute our products.

In addition, the reporting of adverse safety events involving daratumumab, ofatumumab or our product candidates, or public rumors about such events, could cause our stock price to decline or experience periods of volatility. There are no assurances that patients receiving daratumumab, ofatumumab, teprotumumab or our product candidates will not experience serious adverse events in the future.

We have received Fast Track Designation ("FTD"), and Breakthrough Therapy Designation ("BTD"), for certain indications in the past and may seek FTD or BTD, or may seek to participate in other programs for expedited development or review, in the future. We may fail to obtain such designation and may not be eligible for participation in such programs, and even if received, such designations or programs may not lead to a faster development or regulatory review or approval process.

If a product candidate is intended for the treatment of a serious or life-threatening disease or condition, and pre-clinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a product sponsor may apply for FTD from the FDA for such indication. Similarly, the FDA may grant BTD to expedite the development and review of products that treat serious or life-threatening diseases when "preliminary clinical evidence indicates that

the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." In addition, the FDA or other regulatory bodies periodically introduce other programs for expedited review of applications, including the FDA's Real-Time Oncology Review ("RTOR"), Pilot Program, which is currently available for certain supplemental applications for already-approved cancer drugs, and the FDA's priority review designation. The RTOR Pilot Program allows the FDA to review data before the applicant formally submits its completed supplemental application, resulting in a more efficient review when the applicant submits the full supplemental application. Priority review is an FDA designation under which the FDA sets the target date for FDA action on a BLA or supplemental BLA ("sBLA") at six months after the FDA accepts the application for review, rather than the standard 10-month FDA review period. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition.

Although these designations and pilot programs are intended to expedite the review and approval of drug candidates, they do not ensure that marketing approval will be granted in a particular timeframe or at all. The FDA and other regulatory authorities have broad discretion whether or not to grant these designations or include product candidates within pilot programs, and, even if we or our partners believe a particular product candidate is eligible for these designations or programs, we cannot assure you that such authority would agree. Even if we or our partners receive such designations or are eligible for inclusion in expedited review pilot programs in the future, we may not experience a faster development, review or approval process compared to conventional procedures. In addition, such designations or processing under such pilot programs may be withdrawn if the FDA or the relevant regulatory body no longer believes such product candidate meets the criteria for the designation or program. Furthermore, these designations and pilot programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for product candidates granted expedited review or BTD or FTD designation may be denied based on study data, study design or other factors. See also "-We and our partners have conducted and intend to conduct additional clinical trials for selected products and product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations due to the study design and conduct, trial population or for other reasons, or may require additional U.S.-based trials." See "Item 4.B—Business Overview—Government Regulation" for more information about BTD and FTD and other programs for expedited review.

Daratumumab has received BTD for three indications of R/R MM and FTD for one indication of R/R MM and teprotumumab has received BTD and FTD for the treatment of Graves' Orbitopathy (also known as thyroid eye disease). These products have been approved for each of the designated indications and these designations are not applicable to ongoing studies for daratumumab and teprotumumab in other indications. We or our partners may seek FTD or BTD or seek eligibility for other expedited review or approval programs for some or all of our other product candidates in the future, but we may never receive such designation or be accepted to such program, and, even if received or accepted, the development or regulatory review of our product candidates may not be expedited or benefited by such designation or program. In addition, such designation or acceptance to such program does not assure ultimate approval by the FDA or the applicable regulatory body.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us or our partners to modify such programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

To help patients afford our products, certain of our partners have, and we may have in the future, patient assistance programs and we or our partners also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients in affording pharmaceuticals have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient assistance programs and support of independent charitable patient support foundations under a variety of U.S. federal and state laws. At least one insurer also has directed its network pharmacies to no longer accept manufacturer co-payment coupons for certain specialty drugs the insurer identified. Our or our partners' patient assistance programs and support of independent charitable foundations could become the target of similar litigation.

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. For example, the Office of Inspector General of the U.S. Department of Health & Human Services ("OIG"), has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations that provide co-pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. If we, our partners or our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we or such partner could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from the OIG and other enforcement authorities seeking information related to their patient assistance programs and support. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our partners, employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

### We currently rely on a limited number of contract manufacturers to produce our product candidates for clinical trials and are currently negotiating arrangements for commercial scale production.

To ultimately be successful, our antibody products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. Janssen is responsible for the manufacture of daratumumab, Novartis for the manufacture of ofatumumab, Horizon is responsible for the manufacture of TEPEZZA, and Seagen will be responsible for the manufacturing of tisotumab vedotin. For the products we are entirely responsible to manufacture, we currently rely primarily upon one single source third-party CMO, Lonza Group AG ("Lonza"), to manufacture and supply large quantities of our product candidates. We expect to negotiate contracts for commercial production on a product-by-product basis for products that we choose to commercialize ourselves.

We are aware of only a limited number of companies on a worldwide basis who operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin producing antibodies under cGMP. We cannot be certain that we will be able to contract with any of these companies on acceptable terms, if at all. New suppliers would also need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such ingredients. In addition, significant cancellation penalties and the long lead times required for initial orders or to make any changes to existing orders, including changing the scale of production, limit our flexibility in connection with product development, clinical trials or commercial sales. For example, we may be required to order products for the second part of a clinical trial or for a proposed follow-on clinical trial before we have initial results from the study, which could result in loss if we terminate the study or need to make changes to the product.

# We and our manufacturing partners must obtain and maintain compliance with applicable laws and regulations, including cGMPs.

Before commercializing new pharmaceutical and biologic products, manufacturers must comply with the laws and regulations, including drug and biologic cGMPs, of the applicable governmental authorities. Compliance with cGMP regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturing facilities are also subject to pre-approval and ongoing periodic inspection by applicable governmental agencies, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of products employing our technology. The FDA, the EMA or similar regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products.

Manufacturers of pharmaceutical and biologic products often encounter difficulties in production, including difficulties with production yields, stability of the product candidate, quality control and assurance, shortages of qualified personnel, compliance with relevant regulations, production costs and development of advanced manufacturing techniques and process controls. If our manufacturer were to encounter any of these difficulties or otherwise fail to

comply with its obligations to us or under applicable regulations, our ability to provide study materials in our pre-clinical studies and clinical trials would be jeopardized. Any delay or interruption in the supply of pre-clinical study or clinical trial materials could delay the completion of our pre-clinical studies and clinical trials, increase the costs associated with maintaining our pre-clinical study and clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the studies and trials completely.

In addition, we have little control over our manufacturers' compliance with these regulations and standards and manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other regulatory requirements. The discovery of manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with cGMP or other requirements after approval of a product may result in restrictions on the marketing of a product, revocation of the license, withdrawal of the product from the market, seizures, injunctions, fines or criminal sanctions. If the safety of any product supplied is compromised due to the manufacturers' failure to adhere to applicable laws or for other reasons, we or our partners may not be able to obtain regulatory approval for or successfully commercialize such products, and we or our partners may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our products and product candidates or entail higher costs or impair our reputation. No assurance is given that third-party manufacturers will be able to comply adequately with the applicable regulations.

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, or earlier than we anticipate.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to antibody therapy. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs. In addition, many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same indications that our products and product candidates are designed and being developed to treat. For example, Sanofi's isatuximab, a mAb targeting CD38, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a PI. Genentech's ocrelizumab, a mAb targeting CD20, was approved as Ocrevus by the FDA initially in 2017 and is currently approved for RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. We are also aware of other companies that have or are developing technologies that may be competitive with ours, including bispecific, ADC, CAR modified T-cell ("CAR-T"), and ribonucleic acid ("RNA")-based, technologies. In addition, our DuoBody and other technology partners may develop compounds utilizing our technologies that may compete with product candidates that we are developing. See "Item 4.B—Business Overview—Competition" below for more information about our competitors.

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA-approved biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior approvals in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar

applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, the ultimate impact of the BPCIA is subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to U.S. congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In the European Union, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued since 2005. We are aware of many pharmaceutical and biotechnology and other companies that are actively engaged in research and development of biosimilars or interchangeable products.

It is possible that our competitors will succeed in developing products and technologies that are more effective than our products and product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar or interchangeable products for our products or our product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of our products or our product candidates.

In addition, the pricing of our products depend, and the pricing of our products and product candidates, if and when approved for marketing, will depend, in part, on the pricing strategies adopted by our competitors. If we or our partners are forced to reduce the prices of our products, or if sales of our products fall, due to competitive pricing, our revenue from milestone payments, sales or royalties related to such products will be negatively affected.

Our products may face increasing pricing and reimbursement pressure through government and third party decisions to reduce cost or limit physician choice. We may face increased competition from lower-cost products imported from other countries.

The success of our currently commercialized products as well as that of our future potential product launches depends, in part, on the access, pricing and reimbursement environment. There is increasing pricing & reimbursement pressure in many countries that is manifested through government and third party price controls, increased public pressure on price increases, increasing cost containment and formulary restriction policies including but not limited to reference pricing, health technology assessment, pathways, contracting, as well as regulatory reform intended to limit health care provider and patient choice and/or reduce the cost of medicines.

Any products we or our partners are able to commercialize in the United States and the European Union may be subject to competition from lower-priced imports of those same products, leading to reduced revenues and lower sales margins, as well as lower-priced imports of competing products from Eastern Europe, Canada, Mexico and other countries with government price controls or other market dynamics that, in each case, reduce prices of products. The ability of patients and other customers to obtain these lower-priced imports has grown significantly. Some of these foreign imports are illegal under current law. However, the volume of imports is now significant, due in part to the limited enforcement resources and the pressure in the current political environment to permit the imports as a mechanism for expanding access to lower-priced medicines. Parallel importation or importation of foreign products could adversely affect our future profitability. This impact potentially could become even greater if there is a further change in relevant protective legislation or if state or local governments take further steps to import products from abroad.

Even if any of our product candidates receive marketing approval or if any of our marketed products receive marketing approval for additional indications, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval or if any of our marketed products receive marketing approval for additional indications, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well-established in the medical community, and doctors may continue to rely on these treatments. If our products or product candidates do not achieve an adequate level of acceptance, our commercial opportunity may be limited and/or our revenues from sales of these products may be negatively impacted. The degree of market acceptance of our product candidates and new indications for our marketed products, if approved for commercial sale, will depend on a number of factors, including the price, efficacy, safety, convenience and ease of administration of such products, along with their competitive advantages vis-à-vis other therapies, designation as a first-, second- or third-line treatment and any labeling restrictions or warnings. The processes developed for safe administration and any changes to the standard of care for the targeted indications may also have an impact on market acceptance of such products. The willingness of the target patient population to try, and of physicians to prescribe, the product, as well as the availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors are also key factors that impact market acceptance of a new product. In addition, the strength of the sales, marketing and distribution support provided by us or our partners will play a key role in the effective commercialization of a new product.

Our target patient population may be lower than our estimates and we may be unable to recoup our investment due to small patient population or restrictions to the approved indication of a product.

Periodically, we and our partners make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding product development strategy, including determining indications on which to focus in preclinical or clinical trials. These estimates may be inaccurate or based on imprecise data, or patient incidence and prevalence for selected indications may evolve over time as treatments and patient outcomes change. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which could materially adversely affect our business, financial condition, results of operations and future growth prospects.

Even if our product candidates obtain significant market share for their approved indications, because certain potential target populations are small, we may never recoup our investment in such product candidate without obtaining regulatory approval for additional indications for such product candidates. In addition, we expect that we or our partners will initially seek approval of some of our product candidates as second- or third-line therapies for patients who have failed other approved treatments, which further limits the size of the potential patient population for such indication. For product candidates that prove to be sufficiently beneficial as second- or third-line therapies, we expect that we or our partners would seek approval of such products as a second-line therapy (with respect to products initially approved as third-line therapies) and/or as frontline therapies. However, such applications may require us or our partners to conduct additional clinical trials at significant cost and risk, and there can be no assurance that such clinical trials or regulatory applications would be successful. If we or our partners are unable to obtain regulatory approval for such products for frontline or second-line therapy, we may be unable to recoup our investment in such products.

We may need to raise additional funding, which may not be available on acceptable terms, or at all, and failure to obtain this capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing our proprietary product candidates through clinical development and are conducting preclinical studies with respect to other programs. Developing product candidates is expensive, time-intensive and risky, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we seek to advance our proprietary product candidates toward commercialization. In addition, we expect our general and administrative expenses to increase over the next few years as we continue to build and eventually expand our commercialization capabilities in a number of jurisdictions. Although we believe that our existing revenue streams will be sufficient to fund our current projects and commercialization activities, our operating plans may change as a result of a variety of factors, and we may need to seek additional funds sooner than planned through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. Further, we may seek additional capital if market conditions are favorable or if we have specific strategic objectives which could benefit from additional capital.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our ADS holders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of the ADSs to decline. The sale of additional equity or convertible debt securities could be dilutive to our ADS holders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with partners or at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or proprietary product candidates or otherwise agree to terms unfavorable to us. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any proprietary product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, any of which could impair our business, financial condition, results of operations and future growth prospects.

We expect to incur higher research and development costs and general and administrative expenses in future periods as we advance our proprietary product candidates through clinical development and expand our commercialization capabilities.

We expect to incur higher research and development costs in future periods, including increasing costs for clinical trials and manufacturing as our proprietary product candidates advance in clinical development and as we increase the number of product candidates under active clinical development. Our ongoing research and development and, increasingly, pre-launch commercial activities will require substantial amounts of capital and may not ultimately be successful. Over the next several years, we expect that we will continue to incur substantial expenses, primarily as a result of activities related to the continued development of our clinical pipeline and the build-up of our late-stage development and commercialization capabilities. Our proprietary product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and develop into commercially viable products, if at all. Our commitment of resources to the research and continued development of our product candidates and the expansion of our pipeline will likely result in our operating expenses increasing and/or fluctuating as a result of such activities in future periods. We may also incur significant milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

We also expect our general and administrative expenses to increase over the next few years as we continue to build and eventually expand our commercialization capabilities in a number of jurisdictions. In addition, we expect the structure and composition of our staff and expenses to change as we focus on advancing our proprietary product candidates and develop our late-stage development and commercialization capabilities.

We have revenues and expenses in foreign currencies and we have invested a part of our cash position in both Danish and foreign marketable securities and are therefore exposed to different kinds of financial risks including foreign exchange risk, changes in interest rates and credit risks.

Most of our financial transactions are made in Danish kroner, U.S. dollars and Euro. As our reporting currency is Danish kroner, we experience exchange rate risk with respect to our holdings and transactions denominated in currencies other than Danish kroner. Our U.S. dollar currency exposure is mainly related to cash deposits, marketable securities,

and receivables related to our collaborations with Janssen, Novartis and Roche (Horizon). In addition, our reported revenue is affected by the translation of milestone payments, royalties and other income denominated in foreign currencies, primarily U.S. dollars, into Danish kroner as our reporting currency.

We do not generally hedge our currency exposure on our milestone payments, royalties or other income and expense items in the ordinary course of business. Due to long-standing policy of Danmarks Nationalbank with respect to the €/DKK exchange rate, we believe that there are currently no material transaction exposure or exchange rate risks regarding transactions in Euros. However, should Denmark's policy towards the Euro change, the DKK values of our Euro-denominated assets and costs could be materially different compared to what is calculated and reported under the existing Danish policy towards the €/DKK exchange rate.

If we fail to manage our financial risks adequately, our business, financial condition, results of operations and future growth prospects and the value of our ADSs may be adversely affected.

### We may face product liability claims related to the use or misuse of our products or technologies.

Our business exposes us to potential product liability risks which are inherent in research and development, preclinical and clinical testing, manufacturing, marketing and use of antibody products. Product liability claims may be expensive to defend and may result in judgments against us which are potentially punitive. It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical trials. Although we believe that our current coverage limits are adequate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms. Any claims against us, regardless of their merit, could cause our business to suffer. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in decreased demand for our products, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals or labeling, marketing or promotional restrictions, exhaustion of any available insurance and our capital resources, the inability to commercialize any product or product candidate, loss of any potential future revenue and a decline in the market price of our ADSs.

### Our internal computer systems, or those of our partners or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our business and product development.

Our computer systems, including those hosted by third parties, and those of our partners and other contractors or consultants, may be vulnerable to cyber security breaches, computer viruses and unauthorized access, as well as damage or loss of data due to natural disasters, terrorism, war and telecommunication and electrical failures. Our vulnerability to such events may increase while employees work remotely during the COVID-19 pandemic and in the future. Employees may have to use their own devices without dedicated support and security, the number of devices used by employees and the amount of traffic on secured corporate networks can increase, and preventing unauthorized access to networks may be more challenging. These and other factors can be exploited to facilitate phishing, malware or other attacks on our systems. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. In addition, any loss or disclosure of trade secrets, clinical data or other proprietary information as a result of such disruption or breach could subject us to litigation or regulatory review and sanctions and may impact our reputation and our and our partners' ability to further develop and commercialize our products and product candidates, any of which could have a material adverse effect on our business, financial condition, results of operations and the market price of our ADSs.

### We may acquire businesses or products, or form collaborations, in the future, and we may not realize the benefits of such acquisitions or collaborations.

Should attractive opportunities arise, we may acquire companies or technologies that facilitate our access to new medicines, research projects or geographical areas, or that enable us to achieve synergies with our existing operations. However, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in

particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions on favorable terms and could be led to finance these acquisitions using cash and marketable securities that could otherwise be allocated to other purposes in the context of our existing operations, or issuances of equity or convertible debt securities, which could be dilutive to our shareholders and ADS holders and adversely affect the market price of our ADSs. If we acquire or enter into collaborations with businesses with promising markets or technologies, we may not be able to realize the benefits of such acquisitions or collaborations, including if we are unable to successfully integrate them with our existing operations and company culture, or if we encounter difficulties in developing, manufacturing and marketing any new products resulting from such acquisitions or collaborations. We cannot assure you that we will achieve the expected synergies to justify any such transaction, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects and our investors' ability to realize on their investment.

### As a result of the listing of the ADSs on the Nasdaq Global Select Market, we are subject to the Foreign Corrupt Practices Act.

As a result of the listing of the ADSs on the Nasdaq Global Select Market, we are subject to the Foreign Corrupt Practices Act ("FCPA"), which generally prohibits companies and their intermediaries from making or offering improper payments to non-U.S. officials for the purpose of obtaining or retaining business. The FCPA generally also requires companies listed on a U.S. stock exchange to maintain a system of adequate internal accounting controls and to make and keep books, records and accounts that accurately and fairly reflect transactions and dispositions of assets. Because of the predominance of government-sponsored health care systems around the world, many of our commercial relationships outside the United States are with governmental entities, and personnel of such entities may be considered non-U.S. officials for purposes of the FCPA. Violations of the FCPA and other applicable anti-bribery laws are punishable by criminal fines and imprisonment, civil penalties, disgorgement of profits, injunctions and debarment from government contracts as well as other remedial measures. We have adopted an amended written code of business conduct and other policies and procedures to assist us and our personnel in complying with the FCPA and other applicable anti-bribery laws. However, our personnel and others acting on our behalf could take actions that violate these requirements, which could adversely affect our reputation, business, financial condition and results of operations.

# The COVID-19 pandemic could materially adversely impact our business and financial performance, including our clinical trials, projected regulatory approval timelines, supply chain and revenues.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread worldwide and has been declared a global pandemic. COVID-19 has resulted in global business and economic disruption, as many jurisdictions have prohibited international travel and implemented social distancing, quarantine and similar measures for their residents to contain the spread of the coronavirus. COVID-19 is also expected to put a strain on the healthcare systems in the major countries where our partners sell our products and where we and they conduct our clinical trials. The COVID-19 pandemic may be prolonged and may have long-term impacts on the development, regulatory approval and commercialization of our product candidates and on sales of our approved products. The longer the pandemic continues, the more severe the impacts described below will be on our business. The extent, length and consequences of the pandemic are uncertain and impossible to predict. Genmab has established a COVID-19 response team, led by the Chief Executive Officer, which is closely monitoring the evolving situation and has developed and implemented precautionary measures, including remote working for the majority of Genmab employees with a small subset of employees on-site to maintain critical laboratory activities that cannot be done remotely. The response team issues regular updates to employees with guidance to help limit the impact of COVID-19 at our workplace and on our communities and ensure business continuity.

The continued spread of COVID-19 globally could adversely affect our and our partners' ability to recruit and retain patients and principal investigators, site staff and other resources for clinical trials, as hospitals and other healthcare providers prioritize resources toward the outbreak and travel restrictions and social distancing impede patient and staff mobility. This is expected to result in delays or deferrals of affected clinical trials. Any changes in clinical trial practices and policies imposed by regulators in response to COVID-19 may also contribute to such delays or deferrals or cause the costs of clinical trials to increase. As the COVID-19 pandemic and global measures to contain it are still developing, the

full extent of the impact of COVID-19 on the clinical development of our product pipeline cannot currently be determined, although such impact may be significant.

COVID-19 may also affect our employees and the employees of our third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. Such employees may be unable to work as a result of sickness or becoming caregivers to sick family members, or may be delayed or limited in their ability to work as a result of measures such as mandatory remote work or suspension of travel. This may, among other things, limit the CROs' ability to commence and conduct our or our partners' clinical trials, as well as to analyze the data from clinical trials that have been completed. Limitations on the work of our employees as a result of COVID-19 may also affect progress on our preclinical pipeline, as access to activities in our research laboratories may be partially or completely restricted.

Delay in presentation of data analysis, disruptions in the business of the FDA or other health authorities as a result of COVID-19 and related containment measures, or delays in necessary interactions with the FDA, other health authorities, local regulators, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees, could result in delays of reviews and approvals, including with respect to our product candidates. For example, this could cause a delay in the approval by U.S. and European regulatory authorities of daratumumab based on the Phase III APOLLO study, a delay in the approval by European regulatory authorities of daratumumab for the treatment of AL amyloidosis based on data from the ANDROMEDA study and ofatumumab for the treatment of RMS based on data from the ASCLEPIOS studies and a delay in the approval by U.S. regulatory authorities of tisotumab vedotin for the treatment of cervical cancer based on data from the innovaTV 204 study.

Disruption in shipping and manufacturing may also negatively affect our supply chain, causing our partners or producers of comparator drugs used in our clinical trials and their respective suppliers to be unable to produce and ship materials required for use in our clinical trials, in sufficient quantities or at all, leading to delay in, or termination of, our and our partners' clinical trials. Supply chain disruption may also affect the manufacturing, shipment and commercialization of approved products. For example, on December 17, 2020, Horizon announced a short-term disruption in the supply of TEPEZZA due to government-mandated orders to produce COVID-19 vaccines, which has dramatically restricted manufacturing capacity available for the production of TEPEZZA at Horizon's drug product contract manufacturer, Catalent. Prolonged disruption in the supply of TEPEZZA or other of our or our partners' products, as a result of COVID-19 or otherwise, may have a material adverse effect on our business, financial condition, results of operation and cash flows.

Any delay or disruption to clinical trials, regulatory submissions and regulatory approvals would jeopardize timelines for developing, receiving approval for, and subsequently commercializing our product candidates, or obtaining label expansion for our existing products, all of which would adversely affect our operations and financial performance.

COVID-19 impacted DARZALEX sales in 2020 and could continue to affect sales of DARZALEX for existing indications, which could reduce our royalty income pursuant to our collaboration with Janssen. Should the resources of healthcare systems worldwide, including in the United States and Europe, become more severely strained by their response to the pandemic or if such strain is prolonged, resources previously devoted to the diagnosis and treatment of MM may be redeployed to addressing COVID-19, resulting in fewer prescriptions and sales of DARZALEX. Additionally, many patients who currently receive DARZALEX are elderly and immunocompromised and, therefore, more susceptible to severe negative impacts from COVID-19. Such patients may be unable to travel to healthcare facilities to receive DARZALEX treatment as a result of mandatory or self-imposed restrictions on local travel or other social distancing measures. Should they contract COVID-19, they may become unable to continue with their DARZALEX treatment, and many such patients may die. Should treatment of current patients with DARZALEX be temporarily deferred or should such patients die, or should there be a delay or reduction in diagnoses of new MM patients and treatment prescriptions as healthcare resources are redeployed, demand for DARZALEX may be reduced. This would lead to a corresponding reduction in DARZALEX sales and a resulting decrease in our revenues from royalties under our collaboration with Janssen, which would adversely affect our financial performance. In addition, the pandemic could result in delays in clinical development, regulatory approval and commercialization of DARZALEX for additional indications.

The full extent and nature of the impact of the COVID-19 pandemic and related containment measures on our business and financial performance is uncertain as the situation continues to develop. The factors discussed above, as well as other factors which are currently unforeseeable, may result in further and other unforeseen material adverse impacts on our business and financial performance, including on the sales of Kesimpta and TEPEZZA, by our partners and on our royalty and milestone income therefrom.

#### Risks Related to Our Intellectual Property

Our ability to compete may decline if we or our partners are unable to or do not adequately protect intellectual property rights or if our intellectual property rights are inadequate for our products, product candidates or future products or product candidates.

Our commercial success and viability depend in part on our and our partners' ability to obtain and maintain adequate intellectual property protection in the United States, Europe and other countries with respect to our existing products, product candidates and processes and related technologies owned by us and to successfully defend these rights against third party challenges, successfully enforce these rights to prevent third-party infringement, as well as our ability to maintain adequate intellectual property protection for any future technologies and products. If we or our partners do not adequately protect our intellectual property, competitors may be able to use our technologies or products and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and significantly reduce our revenues and potential profits.

While we rely on a combination of patents, trademarks and trade secret protection, as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, products, product candidates and proprietary technologies, our strategy and future prospects are based, in particular, on our patent portfolio. We and our partners or licensees will best be able to protect our technologies, products and product candidates and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, effectively protected trade secrets, or other regulatory exclusivities, cover them. However, the process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position and other intellectual property rights of biopharmaceutical companies involve complex legal, administrative and factual questions, and the issuance, scope, validity and enforceability of patents cannot be predicted with certainty. Also, intellectual property rights have limitations and do not necessarily address all potential threats to our competitive advantage. Our and our partners' ability to obtain patent protection for our or their technologies, products and product candidates is uncertain and the degree of future protection afforded by such intellectual property rights is uncertain due to a number of factors, including, but not limited to:

- we or our partners may not have been the first to make or file patent applications for the inventions covered by pending patent applications or issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions and uses thereof;
- any or all of our or our partners' pending or any future patent applications may not result in issued patents;
- any patents issued to us or our partners may not provide a basis for commercially viable products, or may not
  provide any competitive advantages in countries of significant business opportunity;
- third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation
  actions in the U.S. Patent and Trademark Office ("USPTO"), or oppositions in the European Patent Office
  ("EPO"), or observations or protests, or any similar actions in other patent administrative or court
  proceedings worldwide that challenge the validity, enforceability or scope of such patents, which may

result in our patent claims being narrowed or invalidated which could limit our ability to prevent competitors from developing and marketing similar products;

- our or our partners' technologies, compositions and methods may not be patentable;
- others may design around our or our partners' patent claims to produce competitive products or uses which fall outside of the scope of our patents;
- third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology;
- patent terms may be inadequate to protect our competitive position on our technologies, products and product candidates for an adequate amount of time; or
- the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO or similar foreign
  authorities may change the standards of patentability and any such changes could narrow or invalidate, or
  change the scope of, or change the patent lifetime of, our or our partners' patents.

Patent applications may be denied. Issued patents covering our products and product candidates could be found invalid or unenforceable if challenged in court. Patents issued to our partners may not entitle us to royalties on the products that they protect.

Any or all of our or our partners' pending or any future patent applications may not result in issued patents. The determination of patentability by the relevant patent office is complex and may take several years, the breadth of allowed claims is uncertain, and the patent applications may ultimately be denied or result in issued patents with allowed claims that differ from those in the original application. Even if patents do successfully issue and even if such patents cover our technologies, products, product candidates, compositions and methods of use, third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation actions in the USPTO, third-party oppositions in the EPO or observations or protests, or similar actions challenging the validity, enforceability or scope of such patents in other patent administrative proceedings worldwide, which may result in our or our partners' patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendment of such patents in such a way that they no longer cover our technologies, product candidates or competitive products. Further, if we or our partners initiate legal proceedings against a third party to enforce a patent covering our product, product candidate or technology, the defendant could counterclaim that the patent covering our product, product candidate or technology is invalid or unenforceable. In patent litigation in the United States, certain European and other countries worldwide, it is commonplace for defendants to make counterclaims alleging invalidity and unenforceability in the same proceeding, or to commence parallel defensive proceedings such as patent nullity actions to challenge validity and enforceability of asserted patent claims.

In administrative and court actions, grounds for a patent validity challenge may include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness (lack of inventive step) and in some cases, lack of sufficiently teaching, or non-enablement of, the claimed invention. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the patent examiner during prosecution in the USPTO, the EPO or elsewhere, or made a misleading statement during prosecution in the USPTO. Third parties may also raise similar claims before administrative bodies in the USPTO or the EPO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we or the patent examiner were unaware during prosecution.

Further, we cannot be certain that all of the potentially relevant art relating to our patents and patent applications has been cited in every patent office. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technologies, products, product candidates, compositions and methods of use.

Patents issued to our partners may offer protection for sales of the relevant products by our partners against competition from biosimilars or otherwise, but we will only be entitled to royalties and other payments on those sales to the extent provided by the terms of the relevant agreements with our partners.

We currently rely on proprietary technology licensed from third parties and may rely on other third-party licensors in the future. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from these licensors or other third parties, we may not be able to continue developing our products.

We currently in-license certain technology and intellectual property from third parties to be able to use such technology and intellectual property in our products and product candidates and to aid in our research activities. In the future we may in-license technology and intellectual property from additional licensors.

We rely on certain of these licensors to file and prosecute patent applications and maintain patents and otherwise protect the technology and intellectual property we license from them. We have limited control over these activities or any other technology and intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the technology and intellectual property that is licensed to us.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to proceed without making use of the technologies, compositions or methods covered by such third-party intellectual property rights, and may need to attempt to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible at a reasonable cost or at all. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources or greater clinical or commercialization capabilities than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates, products and related proprietary technologies. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to obtain a license under third-party intellectual property rights, any such license may be non-exclusive, which may allow our competitors to access the same technologies licensed to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

Our existing in-licenses impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with these obligations or otherwise materially breach a license agreement, our licensors or partners may have the right to terminate the license. Under the terms of some of the relevant agreements, our partners also have the right to terminate the agreements at their discretion. In the event of termination of any of these agreements, we may not be able to develop or market the products covered by such licensed intellectual property. In addition, any claims asserted against us by our licensors may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims on a country-by-country basis, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent

infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from continuing its activities on the grounds that our patent claims do not cover these activities. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products, which could materially harm our business and negatively affect sales of our products. Similarly, if we assert trademark or trade name infringement claims, a court may determine that the trademarks or trade names we have asserted are invalid or unenforceable, or that the party against whom we have asserted infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks or trade names, which we may need in order to build name recognition with potential partners or customers in our markets of interest, thus this could materially harm our business and negatively affect our position in the marketplace.

In addition, the standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in a U.S. district court or foreign trial-level court, there is always the risk that the infringer will file an appeal and the initial court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted in a manner insufficient to achieve our business objectives.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in certain territories, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which securities analysts or investors could perceive to be negative. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Claims that our products or product candidates or their uses infringe the intellectual property rights of third parties could result in costly litigation, and unfavorable outcomes could require us to pay damages or royalties and could limit our research and development activities or our ability to commercialize certain products.

Even if we or our partners have or obtain patents covering our technologies, products, product candidates, compositions or uses, we or our partners may still be barred from making, using, importing or selling or otherwise exploiting our products, product candidates or technologies because of the patent rights of others. Our competitors have filed, and in the future may file, patent applications covering technology, compositions or products and uses that are similar or identical to ours. There are many issued U.S., European and other worldwide patents relating to therapeutic drugs, and some of these may relate to compounds we or our partners intend to commercialize. Numerous worldwide patents and pending patent applications owned by others exist in the cancer field and may cover products or product candidates which we or our partners are developing. It is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products, product candidates and technologies. We cannot guarantee that our technologies, products, product candidates, compositions and their uses do not or will not infringe third-party patent or other intellectual property rights. Because patent applications usually take 18 months to publish and many years to issue, there may be currently pending applications with patent claims unknown to us or which will change over time and may later result in issued patents that purportedly cover our technologies, products, product candidates or compositions and uses. These patent applications may have been filed earlier than or have priority over patent applications filed by us or our partners. We may be required to develop or obtain alternative technologies, review product design or, in the case of claims concerning registered trademarks, rename our products or product candidates.

Claims that our or our partners' technologies, products, product candidates, compositions or their uses infringe or interfere with the patent rights of third parties, or that we or our partners have misappropriated third-party trade secrets, could result in costly litigation and could require substantial time and money to resolve, even if litigation were avoided. The basis of such litigation could be existing patents or patents that are granted in the future. If we or our partners were to face infringement claims or challenges by third parties, an adverse outcome could subject us or our partners to significant liabilities to such third parties. Litigation or threatened litigation could result in significant demands on the time and attention of our management team. A negative outcome could expose us or our partners to payment of costs, damages and other financial remedies, including in some jurisdictions, increased damages, such as treble damages and attorneys' fees, if we were found to have willfully infringed a patent. Litigation with third parties concerning alleged infringement of their intellectual property rights could require us and our partners to bear substantial costs and impose burdens on our and their management and personnel, even if we or our partners were to ultimately succeed in such proceedings. Costs of patent litigation and awards of damages in patent infringement cases can be significant, and equitable remedies such as temporary restraining orders and injunctions can negatively impact or prevent product development and commercialization. A negative outcome could also lead us or our partners to delay, curtail or cease the development and commercialization of some or all of our products and product candidates, or could cause us or our partners to seek legal or administrative actions against third parties. We or our partners may need to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms, or at all. Even if we are able to obtain licenses from a third party to resolve a dispute, such settlement arrangements could involve substantial costs including one-time and/or ongoing royalty payments.

# If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position would be harmed.

In addition to seeking patent protection for our products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, partners, consultants, advisors, vendors, university and/or institutional researchers and other third parties. We also have entered or seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and once disclosed we may lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable and may be inadequate. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technologies. Competitors could purchase our products and attempt to reverse engineer and replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technologies, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technologies and know-how may incorporate such technologies and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technologies or know-how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us and our competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and processes, our competitive position could be adversely affected, as could our business.

We will not seek to protect our intellectual property rights or technologies in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications due in several stages over the lifetime of patents or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. Filing, prosecuting and defending patents on our technologies, products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive and, therefore, we typically elect to seek less extensive protections in certain jurisdictions only. We may choose not to pursue or maintain protection for particular inventions, products or product candidates. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forego patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products in a manner that exploits our technologies and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States or in Europe, and thus such protection may not be sufficient to prevent or stop infringing activities.

The requirements for patentability may differ from country to country, particularly in developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. Also, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties if the patents are not being exploited within a certain time period. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country or region-by-region basis, which is an expensive and time consuming process with uncertain outcomes. If we fail to timely file a patent application in a specific country or major market, we may be precluded from doing so at a later date. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings and legal actions to enforce our patent rights in the United States or in Europe and in foreign jurisdictions can be expensive, could result in substantial costs, and could divert management time and our efforts and attention from other aspects of our business. In addition, such proceedings or legal actions could put our patents at risk of being invalidated, found unenforceable or interpreted narrowly, could put our patent applications at risk of not being issued and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may or may not choose to pursue litigation or other actions against those that have infringed our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

In addition, changes in the law and legal decisions by courts in the United States, Europe and foreign countries may affect our ability to obtain adequate protection for our technologies, products, product candidates or compositions or uses thereof and the enforcement of intellectual property.

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third parties may challenge the inventorship of our patent filings and other intellectual property or may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with our partners that provide for the ownership of intellectual property arising from our

collaborations. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from collaboration. Disputes may arise with respect to ownership of the intellectual property developed pursuant to such collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business, financial condition, results of operations and future growth prospects.

# Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products and processes.

Recent patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had conceived or reduced to practice the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our partners fail to maintain the patents and patent applications

covering our products, product candidates, technologies or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

### Patent terms may be inadequate to protect our competitive position on our products and product candidates for an adequate amount of time.

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our products and product candidates are obtained, once the patent term has expired for patents covering a product or product candidate, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products or product candidates similar or identical to ours.

# Third parties may assert that our employees or consultants or we have wrongfully used or disclosed confidential information or misappropriated trade secrets, or claim ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, and no such claims against us are currently pending, we may be subject to claims that we or our employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and could otherwise adversely impact our business.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

# Our collaboration and intellectual property agreements with our partners or other third parties may be interpreted differently by us and our partners or other third parties.

Certain provisions in our collaboration and intellectual property agreements, including the agreements governing our product or technology collaborations and in-licenses of third-party intellectual property or technology, may be interpreted differently by us and our partners or other third parties. From time to time, we have discussions or disagreements with our partners or other third parties regarding the interpretation of our contracts with them. The resolution of any contract interpretation disagreement or dispute could affect the scope of our rights to the relevant intellectual property or technology, or otherwise affect our financial (including with respect to reimbursements, fees, milestones and royalties) or non-financial rights and obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

### If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest.

If we do not own or control trademarks associated with our products, product candidates or technologies, we may not be in control of defending against any claims brought against those trademarks. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively, and our business may be adversely affected.

In addition, any proprietary name we propose to use with any of our product candidate in the United States or other jurisdictions must be approved by the FDA, the EMA or other governmental authorities, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

#### Risks Related to Government Regulation

Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenue.

Sales of certain of our products and our product candidates, if and when approved for marketing, have and will depend, in part, on the extent to which our products will be covered by third-party payors, such as U.S. government health care programs like Medicare and Medicaid, commercial insurance and managed healthcare organizations. These third party payors play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to coverage and reimbursement for our product candidates. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product. The primary trend in the U.S. healthcare industry and elsewhere has been cost containment, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products and/or biosimilars. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Adoption of price controls, cost containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results.

Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product. For example, Medicare reimbursement under the Medicare Physician Fee Schedule is updated on an annual basis. The Medicare Access and CHIP Reauthorization Act of 2015 instituted a 0.5% payment update for July 2015 through the end of 2019, and a 0% payment update for 2020 through 2025, along with a merit-based incentive payment system beginning January 1, 2019, that will replace current incentive programs. For 2026 and subsequent years, the payment update will be either 0.75% or 0.25% depending on which Alternate Payment Model the physician participates.

In addition, in certain jurisdictions, marketing approval for a product, or the ability to launch an approved product, is subject to determination of pricing and reimbursement levels. In such jurisdictions, even if we or our partners are able to obtain marketing approval for our products, commercialization of our products may be significantly delayed or prevented altogether if we are unable to secure reimbursement for our products, at competitive levels or at all.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new

products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products.

Even if approved, our products will be subject to extensive post-approval regulation, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. For U.S. approvals, the holder of an approved BLA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the BLA. In addition, the FDA strictly regulates the promotional claims that may be made about pharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. In addition, we or our partners may be subject to significant liability if physicians prescribe any of our products to patients in a manner that is inconsistent with the approved label and if we are found to have promoted off-label uses of such products. For example, the U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's cGMP requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. In addition, any regulatory approvals that we or our partners receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

Sales, marketing and scientific/educational grant programs in the United States must comply with the U.S. Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veteran's Health Care Act, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Within the European Union, once a Marketing Authorization is obtained, numerous post-approval requirements also apply. The requirements are regulated by both EU regulations (such as reporting of adverse events, etc.) as well as national applicable regulations (related to, for example, prices and promotional material). In addition, as part of its marketing authorization process, the EMA may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use ("CHMP"), to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that target the treatment, prevention, or medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products. The granting of a conditional marketing authorization is restricted to situations in which only the

clinical part of the application is not yet fully complete. Incomplete non-clinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied. Certain approvals of DARZALEX and Arzerra in the European Union were initially granted on the basis of conditional marketing authorizations. Each of these conditions have been met.

Other jurisdictions also impose certain post-approval requirements or may grant conditional marketing approvals. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, notices or warning letters, recall or seizure of products, total or partial suspension of production or changes to manufacturing processes, denial or withdrawal of pre-marketing product approvals, import controls, or refusal to allow us to enter into supply contracts, including government contracts, each of which could have a significant impact on our business, financial condition, results of operations, future growth prospects and reputation. In addition, even if we and our partners comply with FDA, EMA and other applicable requirements, new information regarding the safety or effectiveness of a product could lead the FDA, the EMA or other regulatory authorities to modify or withdraw a product approval. Any government investigation of alleged violations of law could also require us or our partners to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our and our partners' ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results could be adversely affected.

#### We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products and product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, the European Union or in other countries. We expect more rigorous coverage criteria in the future in the U.S. healthcare market and an additional downward pressure on the prices that we or our partners receive for approved products, which may trigger a similar reduction in payments from private payors. If we or our partners are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we and our partners are not able to maintain regulatory compliance, we or they may lose any marketing approval that we or they may have obtained, which could adversely impact our business and financial results.

In particular, since its enactment, there have been judicial and congressional challenges to certain aspects of the Affordable Care Act ("ACA") in the United States, as well as efforts by the former administration to repeal or replace certain aspects of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. There is currently uncertainty with respect to the impact any such repeal may have and any resulting changes may take time to unfold, which could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any such legislation or executive action or the impact of potential legislation or executive action on us. Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removes the penalties for not complying with the ACA's individual mandate to carry health insurance. There may be additional challenges and amendments to the ACA in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the U.S. government to recover overpayments to providers from three to five years. These laws may result in additional

reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our outlicensed products and product candidates (if and when approved) and accordingly, our financial results.

Furthermore, the former Trump Administration has taken several executive actions, including the issuance of a number of executive orders, which could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuing guidance, and reviewing and approving marketing applications. It is difficult to predict how these orders will be implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority, or whether they will be rescinded or replaced. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, we and our partners could be limited and/or delayed in obtaining new regulatory approvals or maintaining existing approvals, either of which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

# We are subject to various laws protecting the confidentiality of certain patient health information, and our failure to comply could result in penalties and reputational damage.

Numerous countries in which we, our partners and our third-party contractors, including CROs and CMOs, operate, manufacture and sell our products have, or are developing, laws protecting personal data and the individual's right to privacy as well as the confidentiality of certain patient health information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation ("GDPR"), which became applicable on May 25, 2018, introduced new data protection requirements in the European Economic Area (the 28 member states of the European Union plus Iceland, Liechtenstein and Norway), ("EEA"), and substantial fines for infringements of the data protection rules. For several EEA jurisdictions, the GDPR expanded significantly the jurisdictional reach of EEA data protection law by extending the law's application to the processing of personal data in connection with the offering of goods or services to data subjects located in the EEA and processing personal data in connection with monitoring the behavior of data subjects located in the EEA. The GDPR imposes several increased obligations and specific restrictions on controllers and processors processing personal data including, for example, additional requirements in relation to the information obligation, where applicable, higher standards for organizations to demonstrate compliance, such as obtainment of valid consent or assessment of another legal basis to justify the data processing activities, increased requirements pertaining to health data (including, in certain situations, where such data is key-coded), mandatory data breach notification requirements, appointment of a data protection officer where the core activities of the controller or the processor consist of processing of sensitive personal data (i.e., health data) on a large scale, additional mandatory requirements for the content of data processing agreements with service providers processing personal data, implementation of appropriate technical and organizational measures and expanded rights for individuals over their personal data. This could affect our and our partners or third-party contractors' ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, potentially leading to harm to our business and financial condition. If the measures implemented by us or our partners or service providers in order to comply with the GDPR requirements are not considered sufficient to ensure the necessary compliance level, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity and a potential loss of business. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

While the GDPR, as a directly effective regulation, was designed to harmonize data protection law across the EEA, it does permit member states to legislate in many areas (particularly with regard to the processing of genetic, biometric or health data), meaning that inconsistencies between different member states will still arise. EEA member states have their own regimes on medical confidentiality and national and EEA-level guidance on implementation and compliance practices is often updated or otherwise revised, which adds to the complexity of processing personal data in the EEA.

In addition to the GDPR, we, our partners and our third-party contractors are subject to similar data privacy and confidentiality laws in other countries in which we or they operate or market our products. Such laws and regulations may also impose costly compliance obligations and potentially significant fines or other penalties for non-compliance.

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

As a biotechnology company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We, our partners and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of accidental contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by our partners and by third party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. In addition, European, U.S. federal and state or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. In the event of an accident or environmental discharge, we may be held liable for any consequential damage and any resulting claims for damages, which may exceed our financial resources and may materially adversely affect our business, financial condition, results of operations and future growth prospects and the value of our ADSs.

We are subject to healthcare laws and regulations, which may require substantial compliance efforts and could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings, among other penalties.

Healthcare providers, such as physicians and others, play a primary role in the recommendation and prescription of our products. Our or our partners' arrangements with such persons and third-party payors and our general business operations will expose us or our partners to broadly applicable fraud and abuse regulations, as well as other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products. Restrictions under applicable U.S. federal and state and non-U.S. healthcare laws and regulations include, but are not limited to, the Anti-Kickback Statute, the Beneficiary Inducement Statute, the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, the federal transparency requirements under the Physician Payments Sunshine Act and analogous U.S. state laws. Rules and regulations covering many of the same matters are found in numerous other countries, including in Denmark, and may be more stringent or result in higher exposures than those in the United States.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities

with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. For more information about these and other applicable regulations, see "Business—Government Regulation" below.

### Our employees and partners may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct of our employees and partners. Misconduct by our partners could include intentional failures to comply with legal requirements or the requirements of the FDA, the EMA and other comparable regulatory authorities; failure to provide accurate information to applicable government authorities; failure to comply with fraud and abuse and other healthcare laws and regulations in the United States, Denmark and other jurisdictions; failure to comply with the FCPA and other applicable anti-bribery laws; failure to report financial information or data accurately; or failure to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, bribery and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Our collaboration agreements include provisions regarding regulatory compliance, but it is not always possible to identify and deter misconduct, and the precautions we and our partners take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

#### Risks Related to our Ordinary Shares, ADSs and Foreign Private Issuer Status

#### ADS holders do not directly hold our shares.

Holders of our ADSs are not treated as our shareholders and do not have shareholder rights. Our depositary, Deutsche Bank Trust Company Americas, is the holder of the shares underlying our ADSs. Holders of ADSs have contractual ADS holder rights. The deposit agreement among us, the depositary and all persons directly or indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. ADS holders may only exercise voting rights with respect to the shares underlying their respective ADSs in accordance with the provisions of the deposit agreement, which provides that holders may vote the shares underlying their ADSs either by withdrawing the shares or by instructing the depositary to vote the shares or other deposited securities underlying their ADSs. However, holders may not know about the meeting sufficiently in advance to withdraw the shares and, even if they instruct the depositary to vote the shares underlying their ADSs, we cannot guarantee you that the depositary will vote in accordance with the holders' instructions. Please see the risk factor entitled "—Holders may not be able to exercise their right to vote the shares underlying their ADSs."

In addition to voting rights, holders' right to receive any dividends we declare on our shares, whether in the form of cash or bonus securities, is also more limited than that of our shareholders. For example, we may elect to offer subscription rights to our shareholders without offering such rights directly to ADS holders as such subscription rights will be offered to the depositary as shareholder. The depositary has substantial discretion as to what will happen with any offered subscription rights and may determine that it is not legal or reasonably practicable to make such rights available to ADS holders, in which case the depositary will endeavor to sell such rights and distribute the proceeds to ADS holders, which it may not be able to do at the then-current market price or at all. If the depositary is unable to distribute or sell such rights, they will lapse, and ADS holders will receive no value. For more information, see the description of our securities registered under Section 12 of the Exchange Act included as an exhibit to this Annual Report.

### The trading price of our equity securities may be volatile due to factors beyond our control, and holders of the ADSs could incur substantial losses.

The market prices of the ADSs and shares may be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for the ADSs and shares may be influenced by many factors, including, but not limited to:

- actual or anticipated fluctuations in our financial condition and operating results;
- the release of new data from the clinical trials of our products and product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- · currency fluctuations;
- price and volume fluctuations attributable to inconsistent trading volume levels of our ADSs;
- · additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies, products and product candidates;
- changes to coverage policies or reimbursement levels by commercial third party payors and government
  payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- issuances or sales of our shares or ADSs by us, our insiders or our other shareholders or ADS holders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for the ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares or ADSs at a favorable price or at all, and may otherwise negatively affect the liquidity of the trading market for our ADSs. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of the holders of shares or ADSs were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit, the attention of our senior management would be diverted from the operation of our business, and we could incur significant liabilities, any one of which could have a material adverse effect on our business, financial condition and results of operations.

# If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ADSs and their trading volume could decline.

The trading market for the ADSs and shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. We are currently followed by analysts, but there can be no assurance that these analysts will continue to follow us or that additional securities or industry analysts will commence coverage of us. If no or only limited securities or industry analysts cover our company, the trading price for the ADSs would be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities, publishes inaccurate or unfavorable research about our business or expresses a negative opinion regarding the performance of our securities, or if our clinical trial results or operating performance fail to meet analyst expectations, the price of the ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for ADSs could decrease, which could cause the price of the ADSs and their trading volume to decline.

#### Holders may not be able to exercise their right to vote the shares underlying their ADSs.

ADS holders may only exercise voting rights with respect to the shares underlying their respective ADSs in accordance with the provisions of the deposit agreement and not as a direct shareholder of the Company. In order to vote the shares underlying their ADSs, ADS holders may either withdraw the shares underlying their ADSs or instruct the depositary to vote the shares underlying such ADSs. However, holders may not know about the meeting far enough in advance to withdraw the underlying shares, and after such withdrawal, holders would no longer hold ADSs, but would instead hold the underlying shares directly.

The depositary will try, as far as practicable, to vote the shares underlying the ADSs as instructed by the ADS holders. In such an instance, if we ask for holders' instructions, the depositary, upon timely notice from us, will notify holders of the upcoming vote and arrange to deliver our voting materials to holders. We cannot guarantee that holders will receive the voting materials in time to ensure that holders will be able to instruct the depositary to vote their shares or to withdraw their shares so that they can vote such shares themselves. If the depositary does not receive timely voting instructions from holders, it may give a proxy to a person designated by us to vote the shares underlying their ADSs. Voting instructions may be given only in respect of a number of ADSs representing an integral number of shares or other deposited securities. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that holders may not be able to exercise any right to vote that they may have with respect to the underlying shares, and there may be nothing they can do if the shares underlying their ADSs are not voted as they requested. In addition, the depositary is only required to notify holders of any particular vote if it receives timely notice from holders in advance of the scheduled meeting. Our articles of association permit, in the case of general meetings, notice to be delivered within a relatively short time span, in which case the depositary would not be required to provide holders with notice of and access to such vote.

#### Holders may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying shares.

Holders' ADSs, which will be evidenced by American depositary receipts ("ADRs"), are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of holders' ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to holders' right to cancel their ADSs and withdraw the underlying shares. Temporary delays in the cancellation of holders' ADSs and withdrawal of the underlying shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our shares. In addition, holders may not be able to cancel their ADSs and withdraw the underlying shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities. For more information, see the description of our securities registered under Section 12 of the Exchange Act included as an exhibit to this Annual Report.

#### ADS holders' rights to pursue claims against the depositary are limited by the terms of the deposit agreement.

The deposit agreement governing the ADSs provides that the depositary may, in its sole discretion, require that any dispute or difference arising from the relationship created by the deposit agreement be referred to and finally settled by an arbitration conducted under the terms described in the deposit agreement, although the arbitration provisions do not preclude you from pursuing claims under U.S. federal securities laws in federal courts. Furthermore, if a holder is unsuccessful in such arbitration, the holder may be responsible for the fees of the arbitrator and other costs in connection with such arbitration pursuant to the deposit agreement.

In addition, the deposit agreement provides that, subject to the depositary's right to require a claim to be submitted to arbitration, the federal or state courts in the City of New York have non-exclusive jurisdiction to hear and determine claims arising under the deposit agreement and in that regard, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable U.S. state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the U.S. federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before investing in the ADSs.

If any holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, a holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not enforced, to the extent a court action proceeds, it would proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of, or a disclaimer of liability under, the U.S. federal securities laws and the rules and regulations promulgated thereunder.

#### Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of Denmark. Although our wholly owned subsidiary, Genmab US, Inc., has an office and laboratory space in the United States, substantially all of our assets are located outside the United States. The majority of our directors and senior management reside outside the United States. As a result, it may not be possible to effect service of process within the United States upon such persons or to enforce judgments against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. securities laws.

The United States and Denmark currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a U.S. court, whether or not predicated solely upon U.S. securities laws, would not be enforceable in Denmark.

In order to obtain a judgment that is enforceable in Denmark, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim again with a court of competent jurisdiction in Denmark. The Danish court will not be bound by the judgment by the U.S. court, but the judgment may be submitted as evidence. It is up to the Danish court to assess the judgment by the U.S. court and decide if and to what extent the judgment should be followed. Danish courts are likely to deny claims for punitive damages and may grant a reduced amount of damages compared to U.S. courts.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors or our senior management, or certain experts named herein who are residents of Denmark or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

We are a "foreign private issuer," as defined in the SEC's rules and regulations, and, consequently, we are not subject to all of the disclosure and corporate governance requirements applicable to public companies organized within the United States.

We are a "foreign private issuer," as defined in the SEC's rules and regulations, and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our directors and senior management are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently publish annual and quarterly reports on our website pursuant to the rules of Nasdaq Copenhagen and expect to file such financial reports on an annual and quarterly basis with the SEC, we will not be required to file such reports with the SEC as frequently or as promptly as U.S. public companies and will not be required to file quarterly reports on Form 10-Q or current reports on Form 8-K that a U.S. domestic company would be required to file under the Exchange Act. Accordingly, there may be less publicly available information concerning our company than there would be if we were not a foreign private issuer. In addition, as a foreign private issuer and as permitted by the listing requirements of the Nasdaq Stock Market LLC ("Nasdaq Stock Market"), we will comply with certain home country corporate governance practices rather than the corporate governance requirements of the Nasdaq Stock Market.

#### If we lose our foreign private issuer status in the future, we would incur significant additional costs and expenses.

As a foreign private issuer, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, we could lose our foreign private issuer status in the future. We will next make a determination with respect to our foreign private issuer status on June 30, 2021.

The regulatory and compliance costs to us under U.S. securities laws if we lose our foreign private issuer status would be significantly more than the costs we incur as a foreign private issuer. If we lose our foreign private issuer status, we would be required to report as a U.S. domestic issuer and be subject to other U.S. securities laws applicable to U.S. domestic issuers. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly greater than the costs we incur as a foreign private issuer. For example, as a U.S. domestic issuer, we would be required to file periodic reports and registration statements with the SEC on U.S. domestic issuer forms, which are more detailed and extensive in certain respects than the forms available to us as a foreign private issuer. We would also be required to prepare our financial statements in accordance with U.S. GAAP and modify certain of our policies to comply with corporate governance practices applicable to U.S. domestic issuers. Such conversion and modifications would involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers, which could also increase our costs.

If we are a passive foreign investment company for U.S. federal income tax purposes for any taxable year, U.S. holders of our ADSs could be subject to adverse U.S. federal income tax consequences.

A non-U.S. corporation will be a passive foreign investment company ("PFIC"), for U.S. federal income tax purposes for any taxable year if either (i) at least 75% of its gross income for such taxable year is "passive income" (as defined in the relevant provisions of the U.S. Internal Revenue Code of 1986, as amended ("Code") or (ii) at least 50% of the value of its assets (generally, based on an average of the quarterly values of the assets) during such year is attributable to assets that produce or are held for the production of passive income. Based on the current and anticipated value of our assets and the nature and composition of our income and assets, we do not expect to be a PFIC for U.S. federal income tax purposes for our current taxable year ending December 31, 2021 or in the foreseeable future. However, the determination of whether or not we are a PFIC according to the PFIC rules is made on an annual basis and will depend on the nature and composition of our income and assets and the value of our assets from time to time. Therefore, changes in the nature and composition of our income or assets or the value of our assets may cause us to become a PFIC. The determination of the value of our assets (including goodwill not reflected on our balance sheet) may be based, in part, on the total market value of our shares and ADSs, which is subject to change and may be volatile.

If we are a PFIC for any taxable year during which a U.S. person holds ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. person. See "Item 10.E—Taxation—Material U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

Changes in Danish, U.S. or other foreign tax laws or compliance requirements, or the practical interpretation and administration thereof, could have a material adverse effect on our business, financial condition and results of operations.

We are affected by various Danish, U.S. and foreign taxes, including direct and indirect taxes imposed on our global activities, such as corporate income, withholding, customs, excise/energy, value added, sales, environmental and other taxes. Significant judgment is required in determining our provisions for taxes and there are many transactions and calculations where the ultimate tax determination is uncertain.

Changes in Danish or foreign direct or indirect tax laws or compliance requirements, including the practical interpretation and administration thereof, including in respect to market practices, or otherwise, could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

#### ITEM 4 INFORMATION ON THE COMPANY

#### A. History and Development of the Company

We were incorporated on June 11, 1998 as a private limited liability company ("Anpartsselskab", or "ApS") under Danish law as a shelf company and are registered with the Danish Business Authority (Erhvervsstyrelsen) in Copenhagen, Denmark under registration number (CVR) no. 21023884. Our name was changed to Genmab ApS on November 17, 1998 and we commenced operations in February 1999. On May 31, 1999, we were converted into a public limited liability company ("Aktieselskab", or "A/S") and changed our name to Genmab A/S.

Our shares are listed on Nasdaq Copenhagen under the symbol "GMAB". Our American Depositary Shares ("ADSs") are listed on the Nasdaq Global Select Market ("NASDAQ") in the United States under the symbol "GMAB".

Legal name: Genmab A/S
Commercial name: Genmab

Domicile: Kalvebod Brygge 43, 1560 Copenhagen V, Denmark

Tel: +45 70 20 27 28 Website: www.genmab.com

(The contents of this website are not incorporated by reference

into this Annual Report on Form 20-F.)

Date of incorporation: June 11, 1998

Legal form of the Company: A Danish public limited liability company

Legislation under which the

Company operates: Danish law Country of incorporation: Denmark

The SEC maintains an Internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

#### **B. BUSINESS OVERVIEW**

We are an international biotechnology company specializing in antibody therapeutics for the treatment of cancer and other diseases. Our core purpose is to improve the lives of patients by creating and developing innovative antibody products. Our vision is to transform cancer treatment by launching our own proprietary product by 2025 and advancing our pipeline of differentiated and well-tolerated antibodies. We are building and expanding our late-stage development and commercialization capabilities to allow us to bring our proprietary products to market in the future. We are continuing to build a well-diversified portfolio of products, product candidates and technologies.

In addition to a broad pipeline of differentiated product candidates, our portfolio includes three approved partnered products; daratumumab, marketed by Janssen as DARZALEX (IV formulation) and DARZALEX FASPRO or DARZALEX SC (SubQ formulation approved in the US and Europe, respectively) for the treatment of certain indications of MM, SubQ of atumumab, marketed in the U.S. as Kesimpta by Novartis for the treatment of RMS, and teprotumumab, marketed in the U.S. as TEPEZZA by Horizon for the treatment of TED. We also have a strong pipeline of novel antibodybased product candidates for the treatment of solid tumors and hematological cancers, which are designed to address unmet medical needs and improve treatment outcomes for cancer patients. Our goal in building our pipeline is to retain at least 50% of product rights in selected programs and in geographic areas where we believe we will be able to maximize their value; we consider such products to be "our own" proprietary products. We currently have eight proprietary product candidates in clinical development: tisotumab vedotin, epcoritamab, DuoBody-PD-L1x4-1BB, DuoBody-CD40x4-1BB, HexaBody-DR5/DR5, DuoHexaBody-CD37, DuoBody-CD3x5T4 and HexaBody-CD38. It was determined in November 2020 that an additional clinical-stage product candidate, enapotamab vedotin, would not advance further in development. The IND application for HexaBody-CD38 was submitted to the FDA in October 2020 and the first patient was dosed in March 2021. We also have approximately 20 proprietary and partnered pre-clinical programs. In addition to our proprietary clinical product candidates and our partners' ongoing label expansion studies for daratumumab, of atumumab and teprotumumab, our partners have twelve additional product candidates in clinical development through collaboration agreements with us. Our portfolio also includes four proprietary antibody technology platforms: (i) our DuoBody platform, which can be used for the creation and development of bispecific antibodies; (ii) our HexaBody platform, which can be used to increase the potential potency of antibodies through hexamerization; (iii) our DuoHexaBody platform, which enhances the potential potency of bispecific antibodies through hexamerization; and (iv) our HexElect platform, which combines two HexaBody molecules to maximize potential potency while minimizing potential toxicity by more selective binding to desired target cells. Antibody products created with these technologies may be used in a wide variety of indications including cancer and autoimmune, central nervous system and infectious diseases. These platforms play a key role in building our product pipeline, enhancing our partnerships and generating revenue. We selectively enter into collaborations with other biotechnology and pharmaceutical companies

that build our network in the biotechnology space and give us access to complementary novel technologies or products that move us closer to achieving our vision and fulfilling our core purpose.

The following chart summarizes the disease indications and most advanced development status of our marketed products, each of the proprietary product candidates in our clinical pipeline and the most advanced product candidates in our pre-clinical pipeline.

### Approved Medicines Created by Genmab<sup>1</sup>

Product	Target	Rights	Disease Indications	Most Advanced Development Phase					
				Pre-Clinical	1	1/2	2	3	Approved
DARZALEX (daratumumab) & DARZALEX FASPRO (daratumumab and hyaluronidase-fihj)	CD38	Janssen (tiered royalties to Genmab on net global sales)	Multiple myeloma <sup>2</sup>		H-25 HI				
Daratumumab			AL Amyloidosis <sup>2</sup>						
			Non-MM blood cancers						
Kesimpta (ofatumumab)	CD20	Novartis (royalties to Genmab on net global sales)	Relapsing multiple sclerosis <sup>2</sup>						
TEPEZZA (teprotumumab-trbw)	IGF-1R	Horizon Therapeutics (under sublicense from Roche, royalties to Genmab on net global sales)	Thyroid eye disease <sup>2</sup>						
Teprotumumab			Diffuse cutaneous systemic sclerosis						

#### **Proprietary Product**<sup>3</sup> Candidates

Product	Target	Rights	Disease Indications	Most Advanced Development Phase					
				Pre-Clinical	1	1/2	2	3	Approved
Epcoritamab	CD3, CD20	50:50 Genmab / AbbVie	Relapsed/refractory DLBCL						
			Abbvie	Hematological malignancies					
			B-cell NHL (combo)						
			Relapsed/refractory CLL						
Tisotumab vedotin	TF	50:50 Genmab / Seagen	Cervical cancer						
			Ovarian cancer						
			Solid tumors						
DuoBody-PD-L1x4-1BB (GEN1046)	PD-L1, 4-1BB	50:50 Genmab / BioNTech	Solid tumors						
DuoBody-CD40x4-1BB (GEN1042)	CD40, 4-1BB	50:50 Genmab / BioNTech	Solid tumors						
HexaBody-DR5/DR5 (GEN1029)	DR5	Genmab	Solid tumors						
DuoHexaBody-CD37 (GEN3009)	CD37	50:50 Genmab / AbbVie	Hematologic malignancies						
DuoBody-CD3x5T4 (GEN1044)	CD3, 5T4	50:50 Genmab / AbbVie	Solid tumors						
HexaBody-CD38 (GEN3014)	CD38	Genmab <sup>4</sup>	Hematologic malignancies						

#### Programs Incorporating Genmab's Innovation<sup>5</sup>

Product	Target	Rights	Disease Indications Most Advanced Development Phase						
				Pre-Clinical	1	1/2	2	3	Approved
Amivantamab (JNJ-61186372)	EGFR, cMet	Janssen	Non-small-cell lung cancer (NSCLC)						
Teclistamab (JNJ-64007957)	BCMA, CD3	Janssen	Relapsed or refractory MM						
Mim8	FIX(a), FX	Novo Nordisk	Healthy volunteers & hemophilia A						
PRV-015 (AMG 714)	IL-15	Provention Bio	Celiac disease						
Camidanlumab tesirine (ADCT-301)	CD25	ADC Therapeutics	Relapsed /Refractory Hodgkin lymphoma						
			Solid tumors						
Talquetamab (JNJ-64407564)	GPRC5D, CD3	Janssen	Relapsed or refractory MM						
HuMax-IL8	IL8	BMS	Advanced cancers						
JNJ-70218902	Undisclosed	Janssen	Solid tumors						
JNJ-63709178	CD123, CD3	Janssen	Acute Myeloid Leukemia (AML)						
JNJ-67571244	CD33, CD3	Janssen	Relapsed or refractory AML or MDS						
JNJ-63898081	PSMA, CD3	Janssen	Solid tumors						
Lu AF82422	alpha-Synuclein	Lundbeck	Parkinson's disease						

<sup>&</sup>lt;sup>1</sup>Products developed and marketed by others incorporating Genmab technology and innovation

#### **Our Business Strategy**

Key elements of our strategy to achieve our vision and fulfill our core purpose include:

- Recurring revenue streams from collaborations.
  - DARZALEX: Janssen is seeking to extend the commercial reach of daratumumab through label expansion. We will continue to contribute to the development strategy for daratumumab through a joint development and steering committee with Janssen.
  - Kesimpta: Novartis is investigating the use of ofatumumab for the treatment of RMS. In August 2020, Novartis received approval from the FDA for ofatumumab in RMS. Novartis submitted a marketing authorization application ("MAA") to the EMA in January 2020 and received a positive opinion from the CHMP in January 2021.
  - TEPEZZA: Horizon is investigating the use of teprotumumab for the treatment of TED and diffuse cutaneous systemic sclerosis. In January 2020, Horizon received approval from the FDA for teprotumumab in TED.
- Actively advance and expand our proprietary product pipeline. We are actively advancing our promising proprietary product candidates through development and seek to expand our proprietary product pipeline by developing new products in-house and by partnering selectively.

<sup>&</sup>lt;sup>2</sup>See local country prescribing information for precise indications. <sup>3</sup>Certain product candidates in development with partners, as noted.

<sup>4</sup>Genmab is developing HexaBody-CD38 in an exclusive worldwide license and option agreement with Janssen Biotech, Inc.
5Products under development by a third-party incorporating Genmab technology and innovation

- Strengthen our product portfolio with strategic collaborations and potential acquisitions. We enter into strategic
  product and technology collaborations to build our network in the biotechnology space and to strengthen our
  portfolio with complementary technologies or products. We monitor for potential acquisitions that would advance
  our overall strategy.
- Leverage our proprietary technology platforms. Our leading proprietary antibody technology platforms play a key role in building our product pipeline, enhancing our partnerships and generating revenue. Multiple new product candidates are currently being developed by us and our partners using our technology platforms, including proprietary product candidates created with our DuoBody and HexaBody technologies. We actively seek partners interested in developing potential antibody therapeutics using our technologies.
- Build our translational research capabilities. Leveraging our expertise in antibody technologies and product
  development, we are expanding our translational research capabilities with the goal of building a library of
  antibody therapeutics that can be tailored to patients.
- Build our commercialization capabilities. We are currently building and expanding our commercialization
  capabilities to allow us to bring our own products to market for the indications and in the geographies we
  determine would create value for our customers and shareholders. Our initial focus for commercialization will be
  in the U.S. and in Japan.

#### **Our Products and Product Candidates**

#### Daratumumab (DARZALEX)

Our lead product, daratumumab, marketed as DARZALEX for the treatment of certain MM indications, is a human IgG1k mAb, that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of MM cells. It triggers a person's own immune system to attack cancer cells, resulting in rapid tumor cell death through multiple immune-mediated mechanisms of action and through immunomodulatory effects, in addition to direct tumor cell death via apoptosis, or programmed cell death. When first approved by the FDA in 2015, it was the first human CD38-targeting mAb to reach the market and the first mAb to receive FDA approval to treat MM. DARZALEX is commercialized by Janssen, under an exclusive development, manufacturing and commercialization agreement, which we entered into in 2012.

MM is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells. The 5-year survival rate for MM patients is estimated at 53.9% in the United States, based on 2010–2016 data from the National Cancer Institute Surveillance, Epidemiology, and End Results ("SEER"). The American Cancer Society and the World Health Organization ("WHO"), estimated that approximately 32,270 people in the United States and 176,404 people worldwide respectively would be newly diagnosed with MM in 2020 and approximately 12,830 people in the United States and 117,077 people globally would die from the disease.

The warnings and precautions for DARZALEX include infusion reactions, interference with serological testing and interference with determination of complete response. The most frequently reported adverse reactions (incidence ≥20%) in clinical trials were: infusion reactions, neutropenia, thrombocytopenia, fatigue, nausea, diarrhea, constipation, vomiting, muscle spasms, arthralgia, back pain, pyrexia, chills, dizziness, insomnia, cough, dyspnea, peripheral edema, peripheral sensory neuropathy and upper respiratory tract infection.

#### Existing Marketing Approvals

Janssen has obtained regulatory approvals for DARZALEX in the jurisdictions set forth in the table below, as well as in certain other countries.

### Table of Contents

### DARZALEX (daratumumab) is indicated for the treatment of adult patients:

Jurisdiction	Approval	Key Underlying Clinical Trial(s)
United States: IV infusion		
Relapsed / Refractory MM		
November 2015	Monotherapy for patients who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent	SIRIUS (MMY2002)
November 2016	In combination with Rd or Vd, for patients who have received at least one prior therapy	CASTOR (MMY3004); POLLUX (MMY3003)
June 2017	In combination with Pd for patients who have received at least two prior therapies, including lenalidomide and a PI	EQUULEUS (MMY1001)
August 2020	In combination with Kd for patients with RRMM who have received one to three previous lines of therapy	CANDOR
	1	EQUULEUS (MMY1001)
Frontline MM		
May 2018	In combination with VMP for newly diagnosed patients who are ineligible for autologous stem cell transplant ("ASCT")	ALCYONE (MMY3007)
June 2019	In combination with Rd for newly diagnosed patients who are ineligible for ASCT	MAIA (MMY3008)
September 2019	In combination with VTd for newly diagnosed patients who are eligible for ASCT	CASSIOPEIA (MMY3006)
Split Dosing Regimen		
February 2019	Option to split first infusion over two consecutive days	EQUULEUS (MMY1001)
European Union: IV infusion or Su		,
Relapsed / Refractory MM		
IV: April 2016	Monotherapy for patients whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy	IV: SIRIUS (MMY2002)
SubQ: June 2020	-8	SubQ: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: February 2017	In combination with Rd or Vd for patients who have received at least one prior therapy	IV: CASTOR (MMY3004); POLLUX (MMY3003)
SubQ: June 2020		SubQ: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
Frontline MM		
IV: July 2018	In combination with VMP for newly diagnosed patients who are ineligible for ASCT	IV: ALCYONE (MMY3007)
SubQ: June 2020		SubQ: COLUMBA (MMY3012)/ PLEIADES (MMY2040)

IV: November 2019	In combination with Rd for newly diagnosed patients who are ineligible for ASCT	IV: MAIA (MMY3008)
SubQ: June 2020		SubQ: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: January 2020	In combination with VTd for newly diagnosed patients who are eligible for ASCT	IV: CASSIOPEIA (MMY3006)
SubQ: June 2020		SubQ: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
Split Dosing Regimen		
December 2018	Option to split first infusion over two consecutive days	EQUULEUS (MMY1001)
Japan: IV Infusion		
Relapsed / Refractory MM		
September 2017	In combination with Rd or Vd	CASTOR (MMY3004); POLLUX (MMY3003)
November 2020	In combination with Kd for patients with RRMM who have received one to three previous lines of therapy	CANDOR
Frontline MM		
August 2019	In combination with VMP for newly diagnosed patients ineligible for ASCT	ALCYONE (MMY3007)
December 2019	In combination with Rd for newly diagnosed patients who are ineligible for ASCT	MAIA (MMY3008)
Japan: SubQ Administration		
March 2021	Subcutaneous formulation	COLUMBIA (MMY3012)

DARZALEX FASPRO (daratumumab and hyaluronidase-fihj) SubQ administration is indicated for the treatment of adult patients in the U.S.:

•	Approval	Key Underlying Clinical Trial(s)
United States: SubQ Administration		
Relapsed / Refractory MM		
May 2020	In combination with Rd or Vd, for patients who have received at least one prior therapy Monotherapy for patients who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent	COLUMBA (MMY3012)/ PLEIADES (MMY2040)
Frontline MM		
May 2020	In combination with VMP for newly diagnosed patients who are ineligible for ASCT In combination with Rd for newly diagnosed patients who are ineligible for ASCT	COLUMBA/ PLEIADES
January 2021	In combination with VTd for newly diagnosed patients who are eligible for ASCT	CASSIOPEIA (MMY3006)
AL Amyloidosis		
January 2021	In combination with VCd for newly diagnosed patients	ANDROMEDA (AMY3001)

PI = proteasome inhibitor; Rd = lenalidomide and dexamethasone; Vd = bortezomib and dexamethasone; VMP = bortezomib, melphalan and prednisone; VTd = bortezomib, thalidomide and dexamethasone; ASCT = autologous stem cell transplant; Pd = pomalidomide and dexamethasone; Kd = carfilzomib and dexamethasone; VCd = bortezomib, cyclophosphamide and dexamethasone

#### Pending Regulatory Applications

In addition to the approved indications, three applications for marketing approval of DARZALEX for certain indications are currently pending with applicable regulators. In November 2020, Janssen submitted regulatory applications in Europe and Japan seeking approval of DARZALEX SC in combination with VCd, based on the Phase III ANDROMEDA study. Also in November 2020, Janssen submitted regulatory applications seeking approval of the SubQ formulation of daratumumab to U.S. and European regulatory authorities, based on the Phase III APOLLO study.

The ANDROMEDA and APOLLO studies are described below.

#### **ANDROMEDA (AMY3001)**

Study Design

The Phase III study (NCT03201965) included 388 patients newly diagnosed with AL amyloidosis. Patients were randomized to receive treatment with either SubQ daratumumab in combination with cyclophosphamide (a chemotherapy), bortezomib (a proteasome inhibitor) and dexamethasone (a corticosteroid) or treatment with cyclophosphamide, bortezomib and dexamethasone alone. The primary endpoint of the study is the percentage of patients who achieve hematologic complete response.

Initial Results (Reported May 2020)

In May 2020, we reported topline results that the study met the primary endpoint of percentage of patients with hematologic complete response. Patients in the study treated with daratumumab in combination with VCd had a 53.3% hematologic complete response (" $\mathbf{CR}$ ") compared to 18.1% of patients who were treated with VCd alone (odds ratio of 5.1 (95% CI 3.2 – 8.2, p<0.0001)).

Additional Data
(Presented at
European Hematology
Association ("EHA")
Virtual Congress,
June 2020)

Twice as many cardiac and renal responses on Dara-VCd: Cardiac response:41.5 vs 22.2%, p-value: 0.0029 / renal response: 53.8 vs 27.4%p-value: <0.0001. Overall, daratumumab-VCd was well tolerated. The median treatment duration was 9.6 months for the daratumumab SubQ+VCd group and 5.3 months for the VCd group. Addition of daratumumab to VCd resulted in a statistically significant and clinically meaningful benefit with no new safety signals observed, demonstrating a favorable benefit-risk profile in subjects with newly diagnosed AL amyloidosis.

Efficacy Update
(Presented at American
Society of
Hematology ("ASH")
virtual meeting,
December 2020)

Rates of deep hematologic response (CR per study primary endpoint, involved free light chain ("iFLC") ≤20 mg/L regardless of free light chain ratio ("FLCr"), and difference between involved and uninvolved free light chain ("dFLC") <10 regardless of FLCr) were higher in the daratumumab-VCd group than in the VCd group. Major organ deterioration ("MOD")-PFS was longer in patients achieving deep hematologic responses, regardless of criteria used to define responses.

#### APOLLO (MMY3013)

Study Design

This Phase III (NCT03180736), randomized, open-label, multicenter study included 304 patients with MM who have previously been treated with lenalidomide and a PI. Patients were randomized 1:1 to either receive daratumumab in combination with Pd or Pd alone. In the original design of the study, patients in the daratumumab plus Pd arm were treated with the IV formulation of daratumumab. As of Amendment 1, all new subjects in the experimental arm were dosed with the SC formulation of daratumumab and patients who had already begun treatment with IV daratumumab had the option to switch to the SC formulation. The primary endpoint of the study was PFS. The study was conducted in Europe under an agreement between Janssen, EMN and Stichting Hemato-Oncologie voor Volwassenen Nederland ("HOVON").

Initial Results (Reported July 2020)

In July 2020, we reported that the study met the primary endpoint of improving PFS. Overall, the safety profile of daratumumab SC in combination with Pd was consistent with the safety profile for each therapy separately.

Efficacy and Safety Data (Presented at ASH, December 2020) D-Pd significantly reduced the risk of progression or death by 37% in patients with RRMM who had received ≥1 prior line of therapy vs Pd alone. No new safety concerns were observed. Infusion related reactions were very low; with a median administration time of 5 minutes, D-Pd increases convenience for patients and decreases treatment burden.

#### **Development Status**

Beyond the current labeled indications and pending regulatory applications, Janssen is conducting a comprehensive clinical development program for daratumumab, including multiple Phase III studies for the treatment of various stages of MM, including SMM, frontline MM and R/R MM, with daratumumab alone or in combination with other therapies. The majority of these Phase III studies are utilizing the subQ formulation of daratumumab.

The chart below illustrates the ongoing development of DARZALEX for each disease stage and therapy type.

### DARATUMUMAB DEVELOPMENT COVERING ALL STAGES OF MULTIPLE MYELOMA AND BEYOND-KEY ONGOING\* TRIALS



<sup>\*</sup>Does not include trials that may still be ongoing but have clinical data and/or are the basis for an existing approval.

#### Additional Data of Potential Significance from 2020

In addition to the ANDROMEDA and APOLLO data, which formed the basis of the regulatory submissions referenced above, in October 2020, Genmab announced positive topline results from the second part of the Phase III CASSIOPEIA (MMY3006) study of daratumumab monotherapy as maintenance treatment versus observation (no treatment) for patients with newly diagnosed MM eligible for ASCT. The second part of the study, which is being conducted by the French Intergroupe Francophone du Myelome ("IFM") in collaboration with HOVON and Janssen, met the primary endpoint of improving PFS at a pre-planned interim analysis.

Part 2 of the CASSIOPEIA study is described below.

#### **CASSIOPEIA (MMY3006)**

Study Design

This Phase III study is a randomized, open-label, multicenter study, conducted by the IFM in collaboration with the HOVON and Janssen, which includes 1,085 newly diagnosed subjects with previously untreated symptomatic MM who were eligible for high dose chemotherapy and ASCT. In the first part of the study, patients were randomized to receive induction and consolidation treatment with daratumumab combined with bortezomib, thalidomide and dexamethasone (VTd) or VTd alone. The primary endpoint was the number of patients that achieved a stringent complete response (sCR). In the second part of the study, patients that achieved a response underwent a second randomization to either receive maintenance treatment of daratumumab 16 mg/kg every 8 weeks for up to 2 years versus no further treatment (observation). The primary endpoint of this part of the study is progression free survival.

*Initial Results* (Reported October 2020)

In October 2020, Genmab reported the second part of the study met the primary endpoint of improving PFS at a pre-planned interim analysis (Hazard Ratio = 0.53 (95% CI 0.42 – 0.68), p < 0.0001) resulting in a 47% reduction in the risk of progression or death in patients treated with daratumumab. The safety profile observed in this study was consistent with the known safety profile of daratumumab and no new safety signals were observed.

#### **Key Ongoing Trials**

Janssen's comprehensive clinical development program for daratumumab also includes the following ongoing clinical trials:

#### Daratumumab for High Risk SMM

Janssen is currently conducting several clinical trials to assess whether earlier treatment with daratumumab could be used for patients with high-risk SMM to delay progression to MM, compared with active monitoring. The Phase II 123-patient, randomized, multicenter, open-label CENTAURUS (SMM2001) study is assessing three dose schedules of daratumumab for the treatment of patients with high-risk or intermediate-risk SMM who had a confirmed diagnosis of high-risk or intermediate-risk SMM for <5 years. Initial efficacy data from the CENTAURUS study was reported in December 2018 and it was determined that dose intensity was associated with efficacy. The safety profile of daratumumab monotherapy in SMM remained consistent with other single-agent daratumumab studies, and no new safety signals were observed with longer follow-up.

Janssen used CENTAURUS data to set the dose schedule for the Phase III randomized, open-label, multicenter AQUILA (SMM3001) study, which is designed to assess the efficacy of daratumumab by subQ injection in delaying the progression from SMM to MM in high-risk SMM patients. The AQUILA study recruited patients ( $\geq$ 18 y) who have had a confirmed diagnosis of SMM for  $\leq$ 5 years, have factors indicating a high risk of progression, and have an Eastern Cooperative Oncology Group performance status of  $\leq$ 1, which refers to impact of the disease on the patient's daily living abilities. The primary endpoint is PFS as assessed by an independent review committee. Secondary endpoints include time to biochemical or diagnostic (SLiM-CRAB) progression, overall response rate ("ORR"), CR rate, duration of and time to response, time to first-line treatment for MM, PFS on first-line treatment for MM, incidence of MM with adverse prognostic features and OS. Disease will be evaluated per International Myeloma Working Group response criteria. The study completed enrollment in May 2019 and is currently ongoing.

#### <u>Daratumumab for Frontline Treatment for Transplant Eligible Patients</u>

Janssen is conducting the following Phase III trials for frontline treatment of transplant eligible MM patients:

The Phase III PERSEUS (MMY3014) study is currently ongoing to evaluate the subQ formulation of daratumumab in combination with VRd compared to VRd alone in approximately 690 participants with previously untreated MM. The primary endpoint of the study is PFS from randomization to the date of disease progression or death. Secondary endpoints include MRD-negative rate, ORR, PFS on next line of therapy, OS, time to and duration of response, health-related quality of life, pharmacokinetics, immunogenicity, stem cell yield after mobilization and time to engraftment post-ASCT. The PERSEUS trial completed enrollment in November 2019 and is currently ongoing.

Janssen also announced the Phase III randomized, open-label AURIGA (MMY3021) trial to evaluate subQ daratumumab in combination with lenalidomide as maintenance treatment in approximately 214 patients with newly diagnosed MM who are MRD positive after frontline ASCT and have no prior anti-CD38 exposure, compared with maintenance treatment by lenalidomide alone. The trial is currently recruiting.

#### Daratumumab for Frontline Treatment for Non-Transplant Eligible Patients

Janssen is conducting the following Phase III trials for frontline treatment of non-transplant eligible MM patients:

The Phase III CEPHEUS (MMY3019) study is evaluating the subQ formulation of daratumumab in combination with bortezomib, lenalidomide and dexamethasone, or VRd, compared to VRd alone in approximately 395 participants with frontline MM for whom hematopoietic stem cell transplant is not planned as initial therapy. The primary endpoint of the study is the percentage of participants with negative MRD status, measured after randomization and prior to PD or subsequent anti-MM therapy. Secondary endpoints include PFS, CR, MRD-negativity rate at one year, ORR, VGPR, PFS on the next line of therapy, DoR, health-related quality of life, pharmacokinetics, immunogenicity, and OS. The CEPHEUS trial completed enrollment in September 2019 and is currently ongoing.

#### **Ofatumumab**

Ofatumumab is a human IgG1k mAb that targets an epitope on the CD20 molecule encompassing parts of the small and large extracellular loops. The CD20 molecule is found on the surface of B-cells, the type of cell which is believed to trigger the inflammatory process that leads to MS. The CD20 molecule is not shed from the cell surface and is not internalized following antibody binding. The antigen-binding fragment ("Fab") domain of ofatumumab binds to the CD20 molecule and the fragment crystallizable ("Fc") domain mediates immune effector functions to result in B-cell lysis *in vitro*. Ofatumumab directs the body's immune system to fight normal and cancerous B-cells. Data suggest that possible mechanisms of cell lysis include complement-dependent cytotoxicity ("CDC"), and antibody-dependent, cell-mediated cytotoxicity ("ADCC"). Novartis is responsible for the development and commercialization of ofatumumab in all potential indications and is currently investigating a subQ formulation of ofatumumab for the treatment of RMS.

#### Kesimpta for the Treatment of Relapsing Multiple Sclerosis

MS, is a chronic inflammatory, demyelinating and neurodegenerative disorder of the central nervous system that affects the white and grey matter of the brain and spinal cord. Initial symptoms typically occur between 20 and 50 years of age, and women are three times more likely to develop MS than men. In 2016, it was estimated that MS affects approximately 400,000 individuals in the United States and 2.3 million worldwide, with 53,299 diagnosed incident cases of MS in 2019 in the U.S., Japan and five major EU markets. 85% of MS cases are relapsing remitting MS, characterized by unpredictable recurrent attacks. There is currently no cure for MS. Treatment typically focuses on speeding recovery from attacks, slowing the progression of the disease and managing MS. Ofatumumab is the first fully human anti-CD20 monoclonal antibody administered with a monthly 20 mg subQ dosing regimen in clinical trials.

In August 2020 the FDA approved the use of Kesimpta injection for SubQ use, for the treatment of RMS in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. This

followed an sBLA submitted by Novartis in February 2020, which was accepted by the FDA with priority review. At the end of January 2020, an MAA was submitted to the EMA. Subsequently the CHMP issued a positive opinion in January 2021. In July 2020, Novartis submitted an application for approval in this indication in Japan. The submissions were based on data from the Phase III ASCLEPIOS I & II (NCT02792218 and NCT02792231) and Phase II APLIOS (NCT03560739) trials. The filing in Japan was also based on the Phase II COMB157G1301 (NCT03249714) study.

#### Key Ongoing Trials in RMS

Novartis' clinical development program for ofatumumab also includes the following ongoing or announced Phase III clinical trials:

The Phase III OLIKOS study is a single arm study evaluating the continued efficacy, safety and tolerability of ofatumumab in patients with RMS who are transitioning from a CD20 mAb therapy. The estimated enrollment in the study is 100 patients and the study is currently recruiting.

The Phase III ALITHIOS study is evaluating the long-term safety, tolerability and effectiveness study of ofatumumab in patients with RMS. The purpose of this study is to collect long-term safety, tolerability, effectiveness and health outcomes data in eligible subjects who have participated in a Novartis ofatumumab clinical MS study. The estimated enrollment for this single group assignment study is 2010 participants and the study is currently recruiting.

The Phase III ARTIOS study is an open-label study to evaluate the effectiveness of treatment with ofatumumab in patients transitioning from commonly used oral MS therapies - fingolimod or dimethyl fumarate, due to breakthrough disease. The anticipated enrollment for this study is 550 patients and the study is currently recruiting.

The Phase III STHENOS study is an open-label, rater-blind randomized multi-center parallel-arm active-comparator study to assess the efficacy and tolerability of ofatumumab 20mg SubQ monthly versus first line physician's choice standard of care disease modifying therapy in the treatment of newly diagnosed RMS. The anticipated enrollment for this study is 236 patients and the study is announced but not yet recruiting.

Arzerra for the Treatment of Chronic Lymphocytic Leukemia

Ofatumumab, marketed as Arzerra, was approved for the treatment of certain CLL indications in the United States, the European Union and a number of other countries. In January 2018, Novartis announced its intention to transition the commercial availability of Arzerra to limited availability through managed access programs or alternative solutions for the treatment of approved CLL indications in non-U.S. markets where applicable and allowed by local regulations. Novartis announced that it will work with regulatory authorities to establish managed access programs or alternative solutions so that patients benefiting from Arzerra can remain on treatment. In 2019, marketing authorizations for Arzerra were withdrawn in the European Union and certain other territories. In August 2020, Genmab announced that Novartis planned to transition Arzerra to an oncology access program for CLL patients in the U.S. Arzerra is currently commercially available for approved CLL indications in Japan. Ofatumumab is not in active clinical development in CLL.

#### **Teprotumumab**

Teprotumumab is developed and manufactured by Horizon for the treatment of TED. In February 2019, Horizon reported positive topline results from the Phase III confirmatory OPTIC study of teprotumumab in the treatment of active thyroid eye disease. The study met its primary endpoint showing more patients treated with teprotumumab compared with placebo had a meaningful improvement in proptosis, or bulging of the eye, as 82.9% of patients treated with teprotumumab compared to 9.5% of placebo patients achieved the primary endpoint of a 3mm or more reduction in proptosis (p<0.001). The safety profile of teprotumumab in OPTIC was similar to that seen in the Phase II study with no new safety observations. The drop-out rate was <5% and balanced across placebo and treatment arms. There were no deaths during the study and a total of three serious adverse events: in the placebo arm, one patient had a visual field defect and received orbital decompression surgery and discontinued study; in the teprotumumab arm, one patient had pneumothorax (considered not related to study drug) and another had an infusion reaction that led to discontinuation of

study drug. The vast majority of treatment-emergent adverse events were mild to moderate in intensity and no other adverse events resulted in discontinuation. Horizon submitted a BLA to the FDA in July 2019. The FDA granted priority review to the BLA in September 2019 and teprotumumab was subsequently approved as TEPEZZA in January 2020. Teprotumumab was created by Genmab under a collaboration with Roche and development and commercialization of the product is now being conducted by Horizon under a license from Roche. Horizon is investigating the use of teprotumumab for the treatment of TED and diffuse cutaneous systemic sclerosis.

#### Tisotumab Vedotin

Tisotumab vedotin is an ADC created to target tissue factor ("TF"), a protein involved in tumor signaling and angiogenesis. TF is a transmembrane protein that is the main physiological initiator of coagulation and is involved in angiogenesis, cell adhesion, motility and cell survival. TF is expressed on many solid tumors, including cervical, ovarian, pancreatic, prostate and bladder tumors. The presence of TF is associated with poor prognosis. Based on its high expression on many solid tumors and its rapid internalization, we believe that TF is a suitable target for an ADC approach. Tisotumab vedotin combines our human mAb that binds to TF and Seagen's ADC technology that utilizes a cleavable linker and the cytotoxic drug monomethyl auristatin E. ADCs are mAbs that are linked to cytotoxic or cell-killing agents. Seagen's ADC technology utilizes mAbs that internalize within target cells after binding to a specified cell-surface receptor. Enzymes present inside the cell catalyze the release of the cytotoxic agent from the mAb, which then results in the desired activity, specific killing of the target cell. We are developing tisotumab vedotin in collaboration with Seagen.

Tisotumab Vedotin for the Treatment of Cervical Cancer and Other Solid Tumors

SEER estimated that 13,170 women would be diagnosed with cervical cancer in the United States in 2019, and that 4,250 would die from cervical cancer. The 5-year survival rate for cervical cancer in the United States is 65.8%, based on 2009–2015 SEER data. Globally, the WHO estimated that 570,000 women would be diagnosed with cervical cancer in 2018, the vast majority of those women being in low- and middle-income countries. We and Seagen are currently evaluating tisotumab vedotin for the treatment of cervical cancer and other solid tumors in six clinical studies: innovaTV 204, innovaTV 205, innovaTV 206, innovaTV 207, innovaTV 208 and innovaTV 301.

innovaTV 204 is a single arm, multicenter, international, potentially registrational Phase II trial in patients with cervical cancer who have relapsed or progressed on or after platinum-containing chemotherapy and who have received or are ineligible for bevacizumab, with estimated enrollment of 100 patients. The primary endpoint of the study was ORR as assessed by an independent review committee. The trial also assessed DoR, PFS, OS and safety. Very favorable topline results were announced in July 2020; results from the trial showed a 24 percent confirmed ORR by independent central review (95% Confidence Interval: 15.9% - 33.3%) with a median DOR of 8.3 months. The most common treatment-related adverse events (greater than or equal to 20 percent) included alopecia, epistaxis (nose bleeds), nausea, conjunctivitis, fatigue and dry eye. The data was featured in a late-breaking proffered paper oral presentation at the European Society for Medical Oncology Virtual Congress 2020 in September. Based on this data, a BLA was submitted in February 2021 to support a potential accelerated approval pathway with the FDA.

innovaTV 205 is a Phase I/II study of tisotumab vedotin as monotherapy or in combination with other therapies in subjects with recurrent or stage IVB cervical cancer and innovaTV 206 is a Phase I/II open label, single arm study of tisotumab vedotin monotherapy for patients in Japan with advanced solid malignancies. The first patient in the innovaTV 206 study was dosed in March 2019 with an expansion phase of tisotumab vedotin as monotherapy initiated in August 2019. In December 2019 the innovaTV 205 study was updated to include an arm with weekly dosing of tisotumab vedotin monotherapy. The study is currently recruiting.

Beyond recurrent and/or metastatic cervical cancer, we believe there may be opportunities for tisotumab vedotin in earlier lines of cervical cancer and in other solid tumors that express TF. In 2018, we and Seagen announced innovaTV 207 and innovaTV 208, Phase II studies to assess, respectively, the activity, safety and tolerability of tisotumab vedotin for the treatment of selected solid tumors and the efficacy of tisotumab vedotin for platinum-resistant ovarian cancer. Both studies are currently recruiting.

The first Phase III study of tisotumab vedotin was announced in January 2021. The open-label, randomized, global trial of tisotumab vedotin versus chemotherapy will enroll approximately 482 patients with recurrent or metastatic cervical cancer who have received one or two prior lines of systemic therapy for their recurrent or metastatic disease. Eligible patients will be randomized to receive either tisotumab vedotin 2.0 mg/kg every three weeks or investigator's choice of chemotherapy. The primary endpoint of the study is overall survival. This global study will be sponsored by Seagen in collaboration with Genmab, European Network of Gynaecological Oncological Trial Groups and the Gynecologic Oncology Group. The study is designed to confirm the potential of tisotumab vedotin as monotherapy for patients with metastatic and or recurrent cervical cancer.

#### **Epcoritamab**

Epcoritamab is a proprietary bispecific antibody therapeutic candidate created using our proprietary DuoBody technology. Epcoritamab is designed to target CD3, which is expressed on all T-cell subtypes and is part of the T-cell receptor, and CD20, a clinically well-validated therapeutic target. CD20 is expressed in a majority of B-cell malignancies, including CLL, diffuse large B-cell lymphoma ("**DLBCL**"), follicular lymphoma ("**FL**") and mantle cell lymphoma ("**MCL**"). In a number of laboratory models, epcoritamab has shown high potency in killing CD20+ tumors and induced potent tumor cell lysis across a panel of B-cell tumor lines. We are developing epcoritamab in collaboration with AbbVie.

Epcoritamab for the Treatment of B-cell malignancies

DLBCL is the most common type of non-Hodgkin lymphoma ("NHL") in the United States and worldwide, with an average age at diagnosis of mid-60s. It is an aggressive form of NHL with relative 10-year survival rates of approximately 46% and relative 5-year survival rates of approximately 64%. Prevalence is anticipated to increase, driven by growth in aging populations. DLBCL affects B-lymphocytes and can develop in the lymph nodes or in other organs, and may be either localized or generalized. The prognosis for relapsed or refractory DLBCL patients is poor, especially for those with high-risk factors, and for most patients with refractory DLBCL there are no curative treatment options. We and AbbVie are currently evaluating SubQ epcoritamab for the treatment of B-cell malignancies including DLBCL and CLL in four clinical studies: GCT3013-01, GCT3013-03, GCT3013-04 and GCT3013-05.

The first patient was dosed in the Phase I/II GCT3013-01 safety and efficacy study of epcoritamab for the treatment of B-cell malignancies in July 2018, with initial dose-escalation data presented in December 2019. Updated dose-escalation data was presented at ASH in December 2020, concluding that epcoritamab demonstrates a consistent and favorable safety profile, with no grade  $\geq$ 3 CRS events and limited neurotoxicity, in support of outpatient administration. Emerging data with longer follow-up present substantial single-agent efficacy, including CR in heavily pretreated patients with FL, MCL, and DLBCL. The first expansion cohort was initiated in July 2020 and the trial is currently recruiting. A similar trial, GCT3013-04 is currently recruiting patients in Japan.

GCT3013-03 is a Phase I/II open-label, multi-center safety and efficacy study of epcoritamab in relapsed/refractory CLL. The trial includes two parts, a dose escalation phase (phase Ib) and an expansion phase (phase II). The dose escalation phase is currently recruiting.

GCT3013-05 is the first Phase III study of epcoritamab. The purpose of the open-label, randomized, multi-center trial is to evaluate the efficacy of epcoritamab compared to investigator's choice of chemotherapy in patients with relapsed, refractory DLBCL who have failed or are ineligible for ASCT. Estimated enrollment into the trial is 480 patients and the study is currently enrolling. The first patient was dosed in this study in January 2021. Additional Phase III studies are planned.

#### DuoBody-PD-L1x4-1BB

DuoBody-PD-L1x4-1BB is a bispecific antibody designed to target PD-L1 and 4-1BB to block the inhibitory PD-1/PD-L1 axis and simultaneously activate essential co-stimulatory activity via 4-1BB using an inert Fc backbone. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF receptor super-family and is expressed predominantly on activated T-cells. In pre-clinical settings,

DuoBody-PD-L1x4-1BB promoted conditional T-cell activation in a tumor-specific manner by simultaneous activation and release of the key inhibitory brake. Pre-clinical studies also indicated a release of T-cell inhibition through the PD-1/PD-L1 axis, including in the absence of 4-1BB, strong co-stimulation via the agonistic activity of 4-1BB and T-cell clonal expansion. We are developing DuoBody-PD-L1x4-1BB for the treatment of solid cancers in collaboration with BioNTech using our proprietary DuoBody technology platform and PD-L1 antibody and BioNTech's 4-1BB antibody. A Phase I/II study of DuoBody-PD-L1x4-1BB for the treatment of malignant solid tumors was initiated in May 2019 with the first expansion cohort initiated in the first quarter of 2020. Preliminary clinical data was presented at the SITC 35th Anniversary Annual Meeting in November 2020. The study is currently recruiting.

#### DuoBody-CD40x4-1BB

DuoBody-CD40x4-1BB is a bispecific antibody designed to conditionally activate both CD40-expressing antigenpresenting cells and 4-1BB-expressing T-cells using an inert DuoBody format. In preclinical settings, as presented at European Association for Cancer Immunotherapy Annual meeting in May 2019, the CD40- and 4-1BB-specific Fab arms of DuoBody-CD40x4-1BB bound to primary human CD40-expressing CD20+ B cells and activated 4-1BB-expressing CD3+ T cells. DuoBody-CD40x4-1BB dose-dependently induced CD40 signaling only upon CD40 binding and simultaneous binding to 4-1BB expressing cells and induced 4-1BB signaling only upon 4-1BB binding and simultaneous binding to CD40-expressing cells. DuoBody-CD40x4-1BB was also shown to conditionally increase proliferation of activated T cells in the presence of CD40-expressing cells in vitro. DuoBody-CD40x4-1BB induced T-cell proliferation upon crosslinking of CD40- and 4-1BB-expressing cells and the binding of only the CD40 arm or the 4-1BB arm had no effect on T-cell proliferation. In addition, DuoBody-CD40x4-1BB did not induce proliferation of T cells that had not been activated by polyclonal or antigen-specific T-cell receptor triggering. In the context of cancer, DuoBody-CD40x4-1BB can enhance anti-tumor immunity by (re-)activating tumor-specific T cells, either intratumorally or in the tumor-draining lymph nodes. Conditional agonist activity is a unique mechanism of action, distinguishing DuoBody-CD40x4-1BB from agonistic monoclonal antibodies targeting CD40 or 4-1BB. It therefore represents a novel therapeutic agent with potential for treatment of solid tumors. We are developing DuoBody-CD40x4-1BB for the treatment of solid cancers in collaboration with BioNTech using Genmab's proprietary DuoBody technology platform and BioNTech's CD40 and 4-1BB antibodies. The first patient was dosed in the first-in-human Phase I/II study of DuoBody-CD40x4-1BB for the treatment of malignant solid tumors in September 2019 and the study is currently recruiting.

#### HexaBody-DR5/DR5

HexaBody-DR5/DR5 is a proprietary antibody therapeutic candidate created with our proprietary HexaBody technology. HexaBody-DR5/DR5 consists of two non-competing HexaBody molecules that are designed to target two distinct epitopes on death receptor 5, or "DR5", a cell surface receptor that mediates a process called programmed cell death. Increased expression of DR5 has been reported in several types of tumors. We believe that HexaBody-DR5/DR5 may have potential in treatment of a number of solid cancers. HexaBody-DR5/DR5 is the first HexaBody molecule to enter the clinic. In 2018, we initiated a Phase I/II clinical trial of HexaBody-DR5/DR5, GCT1029-01, for the treatment of solid tumors, with the first patient dosed in May 2018. The study is currently recruiting.

#### DuoHexaBody-CD37

DuoHexaBody-CD37 is a bispecific IgG1, created with our propriety DuoHexaBody technology platform. CD37 is a tetraspanin membrane protein abundantly expressed on normal and malignant B cells and represents a promising target for the treatment of B-cell malignancies. CDC is an efficient effector mechanism employed by multiple existing antibody therapeutics. With DuoHexaBody-CD37 we aimed to generate CD37-specific antibodies with superior CDC activity. In preclinical settings DuoHexaBody-CD37 has been shown to induce potent *in vivo* and *in vitro* anti-tumor activity. As presented at ASH in December 2018, DuoHexaBody-CD37 induced superior CDC activity compared to single HexaBody molecules or the combination thereof in CLL cells ex vivo. In addition, the potency of DuoHexaBody-CD37 was superior to standard-of-care CD20 antibodies *ex vivo*. The encouraging preclinical models suggest DuoHexaBody-CD37 is a promising candidate for clinical development in B-cell malignancies. In March 2020, we initiated a Phase I/II clinical trial of DuoHexaBody-CD37 for the treatment of hematologic malignancies. The study is currently recruiting. We are developing DuoHexaBody-CD37 in collaboration with AbbVie.

### DuoBody-CD3x5T4

DuoBody-CD3x5T4 is a CD3 bispecific, Fc-silenced IgG1 antibody with the capacity to crosslink T cells with 5T4-expressing tumor cells. In preclinical models DuoBody-CD3x5T4 shows potent antitumor activity *in vitro* and *in vivo* in a range of cancer indications. Initial preclinical data for DuoBody-CD3x5T4 was presented at the 34th Society for Immunotherapy of Cancer Annual Meeting in November 2019. Key findings were that DuoBody-CD3x5T4 induced CD4+ and CD8+ T-cell mediated cytotoxicity in 5T4-expressing tumor cell lines derived from a variety of solid cancers. T-cell mediated cytotoxicity was associated with T-cell activation, release of perforin and granzyme B and production of inflammatory cytokines. DuoBody-CD3x5T4 showed anti-tumor activity in breast cancer CDX and lung cancer PDX models in humanized mice, which was associated with peripheral T-cell activation and cytokine production *in vivo*. The broad expression of 5T4 across cancer indications and limited expression in normal cells makes DuoBody-CD3x5T4 a promising novel drug candidate with potential anti-tumor effect across different solid tumor indications. The first CTAs for DuoBody-CD3x5T4 were submitted to authorities in Denmark and Spain in January 2020, followed by the IND, which was submitted to the FDA in February 2020. The first patient was dosed with DuoBody-CD3x5T4 in August 2020. We are developing DuoBody-CD3x5T4 in collaboration with AbbVie.

#### HexaBody-CD38

HexaBody-CD38 is a novel human CD38 monoclonal antibody product incorporating our HexaBody technology. In preclinical models of hematological malignancies, as presented at ASH in December 2019, HexaBody-CD38 demonstrates enhanced CDC and shows potent anti-tumor activity. HexaBody-CD38 carries the E430G mutation that facilitates the natural process of antibody hexamer formation through intermolecular Fc-Fc interactions after antigen binding at the cell surface. Enhanced IgG hexamer formation increases binding of the hexavalent complement component C1q, thereby potentiating or unlocking antibody-mediated CDC. HexaBody-CD38 induced highly potent CDC in vitro in cell lines derived from hematological malignancies including MM, B cell lymphoma and acute myeloid leukemia ("AML"), inducing CDC in seventeen out of twenty-eight tumor cell lines that were not sensitive to daratumumab (<50% tumor cell lysis), including cell lines with low expression of CD38 or high expression of the complement inhibitory protein CD59. HexaBody-CD38 did not induce lysis of normal human B cells, T cells or erythrocytes, and induced minimal lysis of normal human NK cells. In addition, HexaBody-CD38 was consistently more potent than daratumumab in samples from daratumumab-naïve patients (newly diagnosed or relapsed/refractory to standard-of-care, including chemotherapy or high dose chemotherapy followed by ASCT, immunomodulatory drugs and proteasome inhibitors). In June 2019, Genmab entered into an exclusive worldwide license and option agreement with Janssen to develop and commercialize HexaBody-CD38. See below for additional details about this agreement. We submitted an IND to the FDA for HexaBody-CD38 in October 2020 and the first CTA, in Denmark, in November 2020. The first patient was dosed with HexaBody-CD38 in March 2021.

#### Enapotamab Vedotin

Enapotamab vedotin is an ADC created to target to AXL (from anexelekto, or uncontrolled growth), a signaling molecule expressed on many solid cancers and implicated in tumor biology. AXL contributes to tumor progression and has been associated with poor clinical prognosis in many cancer types. Over-expression has been described in solid cancers, including lung, esophageal, ovarian, breast, cervical, thyroid, endometrial and pancreatic cancers. AXL is emerging as a marker in tumors with resistance to therapy (e.g., tyrosine kinase inhibitors, chemotherapy). In addition, over-expression of AXL is observed in advanced tumors with epithelial-mesenchymal transition ("EMT")-like features.

In November 2020, we announced that we would not advance the development of enapotamab vedotin. While enapotamab vedotin has shown some evidence of clinical activity, this was not optimized by different dose schedules and/or predictive biomarkers. Accordingly, the data from the expansion cohorts did not meet Genmab's stringent criteria for proof-of-concept. Enapotamab vedotin is fully owned by Genmab, and the ADC technology used with enapotamab vedotin has been licensed from Seagen.

#### **Pre-clinical Programs**

In addition to our marketed products and clinical product candidates, we have approximately 20 active in-house and partnered preclinical programs.

#### **Partnered Candidates**

As of December 31, 2020, our partners have fifteen product candidates in clinical development through collaboration agreements with us. These include several bispecific antibodies being developed by Janssen using our proprietary DuoBody technology, which are being tested to treat NSCLC, AML, R/R AML or MDS, solid tumors and certain MM indications. Additional products are being developed in partnership with BMS, ADC Therapeutics, Lundbeck, Provention Bio and Novo Nordisk. In December 2020 Janssen submitted a BLA to the FDA and an MAA to the EMA for amivantamab in patients with epidermal EGFR Exon 20 insertion-mutated NSCLC. These are the first regulatory submissions for a product candidate that was created using Genmab's DuoBody technology platform. Amivantamab was also the first DuoBody product to receive BTD from the FDA, which occurred in March 2020.

#### **Our Technology Platforms**

#### **DuoBody Platform**

The DuoBody platform is our innovative proprietary platform for the creation and development of bispecific antibodies. Bispecific antibodies bind to two different epitopes (or "docking" sites) either on the same, or on different targets (also known as dual-targeting). We believe that dual-targeting may improve binding specificity and enhance therapeutic efficacy or bring two different cells together (for example engaging a T-cell to kill a tumor cell). Bispecific antibodies generated with our DuoBody platform can be used for the development of potential therapeutics for cancer, hemophilia and autoimmune, infectious, cardiovascular and central nervous system diseases. DuoBody molecules are designed to combine the benefits of bispecificity with the strengths of conventional antibodies, which may allow DuoBody molecules to be administered and dosed in the same way as other antibody therapeutics. Based on a proof-of-concept study, we believe that our DuoBody platform generates bispecific antibodies via a versatile and broadly applicable process which has the potential to be easily performed at high throughput, at standard bench, as well as on a commercial manufacturing scale. We use the DuoBody platform to create our own bispecific antibody programs and we actively seek partners interested in developing antibody therapeutics using our DuoBody technology. We have a number of commercial partners for the DuoBody technology, including Janssen, BioNTech and Novo Nordisk. See "—Product and Technology Collaborations—Collaborations and Other Agreements for our Partnered Products" for more information about our current licenses and collaborations.

A number of our proprietary bispecific antibodies created with the DuoBody technology are in clinical development. In addition, Janssen has progressed a number of product candidates into clinical development through our DuoBody partnership, including amivantamab, which has been submitted for regulatory approval in the US and in Europe.

#### HexaBody Platform

Our HexaBody platform is a proprietary technology that is designed to increase the potency of antibodies. The HexaBody platform is designed to build on natural biology to strengthen the natural killing ability of antibodies while retaining regular structure and specificity. The HexaBody technology allows for the creation of potentially potent therapeutics by inducing antibody hexamer formation (clusters of six antibodies) after binding to their target antigen on the cell surface. We have used the HexaBody platform to generate antibodies with an enhanced complement-mediated killing design, allowing antibodies with limited or absent killing capacity to be transformed into potent, cytotoxic antibodies. In addition to complement-mediated killing, the clustering of membrane receptors by the HexaBody platform may lead to subsequent outside-in signaling (e.g. in the case of our HexaBody-DR5/DR5 product leading to cell death). The HexaBody technology creates opportunities to explore new product candidates, to repurpose drug candidates unsuccessful in previous clinical trials due to insufficient potency and may provide a useful strategy in product life cycle management. We believe that the HexaBody technology is broadly applicable and may be combined with other antibody

technologies. The technology has the potential to enhance antibody therapeutics for a broad range of applications in cancer and infectious diseases.

HexaBody-DR5/DR5 is our first proprietary antibody created with HexaBody technology to reach clinical development. In addition, in June 2019, we entered into an exclusive license and option agreement with Janssen to collaborate exclusively on a next-generation CD38 antibody product incorporating our proprietary HexaBody technology. The IND for HexaBody-CD38 was submitted to the FDA in October 2020 and the first CTA, in Denmark, was submitted in November 2020. The first patient was dosed with HexaBody-CD38 in March 2021.

#### **DuoHexaBody Platform**

The DuoHexaBody platform is a novel proprietary technology that combines the dual targeting design of our DuoBody technology with the potential enhanced potency of our HexaBody technology, creating bispecific antibodies with a target-mediated enhanced hexamerization design. DuoHexaBody-CD37 is currently our only proprietary bispecific antibody created with DuoHexaBody technology. An IND for DuoHexaBody-CD37 was submitted to the FDA in November 2019 and the first patient was treated with DuoHexaBody-CD37 in March 2020.

#### HexElect Platform

The HexElect platform is a novel proprietary technology that combines two different HexaBody molecules in order to selectively hit only those cells that express both targets by making the activity of complexes of HexaBody molecules dependent on their binding to two different targets on the same cell. The HexElect platform maximizes potency while minimizing potential toxicity, potentially leading to more potent and safer products.

#### **Manufacturing**

We do not currently manufacture the drug products ourselves that we need to conduct our clinical trials, and we therefore rely on our partners or CMOs to supply drug product for our IND-enabling studies, clinical trials and process validation batches and related activities for BLA and other regulatory submissions, and we expect to rely on such partners or CMOs for production of commercial supply of our products in the future. Manufacturing clinical products is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. Our vendors are required to comply with cGMP regulations, which are regulatory requirements enforced by the FDA, the EMA and other regulatory bodies to assure proper design, monitoring and control of manufacturing processes and facilities for human pharmaceuticals.

We have no involvement with the manufacturing process for our partnered approved products, DARZALEX, Kesimpta and TEPEZZA, which are handled by Janssen, Novartis and Horizon, respectively, under the applicable agreements. Currently, the majority of the drug products required for our clinical trials and pre-clinical studies are manufactured by Lonza. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including fill and finish, shipping and storage of drug products and our product candidates. To meet our expected needs for commercial manufacturing in connection with the anticipated commercial launch of tisotumab vedotin, we are currently in negotiations with a CMO to manufacture commercial quantities of tisotumab vedotin, subject to regulatory approval. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. Although we rely on our cGMP manufacturers and suppliers, we have personnel with substantial manufacturing and production experience to oversee our relationships with such manufacturers and suppliers.

While we believe our CMOs are capable of producing sufficient quantities of drug product to support our currently planned commercialization, clinical trials and pre-clinical studies, we also believe that there are a number of alternative third-party manufacturers that have similar capabilities that would be capable of providing sufficient quantities of commercial products and drug product for our planned clinical trials and pre-clinical studies. However, should our CMOs not be able to provide sufficient quantities of commercial products or drug product for our planned commercialization, clinical trials or pre-clinical studies, we would be required to seek other CMOs to provide this drug product, potentially resulting in a delay in such trials or delivery of our commercialized products.

#### **Commercialization Strategy**

Our partnered approved products, DARZALEX, Kesimpta and TEPEZZA, are marketed by Janssen, Novartis and Horizon, respectively, under worldwide license agreements with us, or in the case of TEPEZZA, under a sublicense from Roche. We receive royalties from Janssen, Novartis and Roche based on net sales of DARZALEX, Kesimpta and TEPEZZA, but we are not involved with commercialization activities or strategy. We are currently building and expanding our commercial capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create value for our shareholders. Our goal is to become a commercial-stage company with an initial focus on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer, subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seagen. Under our agreement, Seagen and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. In October 2020, Genmab and Seagen entered into a joint commercialization agreement. Genmab will co-promote tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. In all other markets, if any, Seagen will be responsible for commercializing tisotumab vedotin and Genmab will receive royalties based on a percentage of aggregate net sales ranging from the mid-teens to the mid-twenties. The companies will continue the practice of joint decision-making on the worldwide development and commercialization strategy for tisotumab vedotin. We view Japan as a promising commercial opportunity where modest commercial and medical affairs infrastructure has the potential to become a high-value investment. Given the low rate of cancer screening and human papillomavirus vaccinations in Japan, we believe that cervical cancer presents a significant unmet need in the Japanese medical market. In June 2020, Genmab and AbbVie entered into a broad collaboration agreement to jointly develop and commercialize epcoritamab, DuoHexaBody-CD37 and DuoBody-CD3x5T4. For epcoritamab, the companies will share commercial responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization. Genmab will be the principal for net sales in the U.S. and Japan and receive tiered royalties on remaining global net sales. For DuoHexaBody-CD37, DuoBodyCD3x5T4 and any product candidates developed as a result of the companies' discovery research collaboration, Genmab and AbbVie will share responsibilities for global development and commercialization in the U.S. and Japan, while AbbVie will be responsible for further global commercialization with Genmab having a right to opt-in to co-commercialize in the remaining territories.

Moving forward, we may choose to commercialize new products independently, or we may rely on our partners to do so in whole or in part. This will be determined on a product-by-product or indication-by-indication basis in each proposed market and will depend on the agreements we have with our partners and our assessment of the most effective commercialization plan to benefit patients and create value for our shareholders.

#### Competition

The biotechnology and pharmaceutical industries generally, and the cancer drug sector specifically, are characterized by rapidly advancing technologies, evolving understanding of disease etiology, intense competition and a strong emphasis on intellectual property. While we believe that our product candidates and our knowledge and experience provide us with competitive advantages, we face substantial potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical studies, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. In addition, our competitors' products may be more effective or more effectively marketed and sold than any treatment we or our development partners may

commercialize and may render our product candidates obsolete or noncompetitive before we can recover the expenses related to developing and commercializing our product candidates.

Below is a description of competition in certain of our products and product candidates.

With respect to daratumumab, there are numerous other FDA-approved drugs for the treatment of MM, including immunomodulating agents such as Celgene's Revlimid and Pomalyst®, PIs such as Janssen and Takeda's Velcade®, Amgen's Kyprolis®, and Takeda's Ninlaro®, histone deacetylase inhibitors such as Novartis' Farydak® and mAbs such as BMS' Empliciti®. Several of these drugs are used in combination with chemotherapy and corticosteroids. The competition daratumumab faces from these and other therapies is intensifying. Additionally, isatuximab, a CD38 antibody developed by Sanofi, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a PI. The IKEMA trial of isatuximab + Kd in second line MM met its primary endpoint of improving PFS in May 2020. Sanofi filed for approval in this indication with a decision from the FDA expected by July 2021. In January 2020, GlaxoSmithKline announced a head-to-head trial of belantamab mafodotin, a humanized B-cell maturation antigen ("BCMA") ADC, in combination with bortezomib and dexamethasone versus daratumumab in combination with bortezomib and dexamethasone in patients with relapsed/refractory MM. In addition, belantamab mafodotin was approved as BLENREP in August 2020 as monotherapy for adults w/ RRMM who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a PI and an immunomodulatory agent. We are also aware of numerous additional investigational agents that are currently being studied. If any of these investigational agents are successful, they may compete with daratumumab in the future. Data have also been presented on several developing technologies and related potential products, including bispecific antibodies, ADCs and CAR-Ts that may compete with daratumumab in the future.

In August 2020 the FDA approved subQ ofatumumab for the treatment of RMS in adults. An MAA was submitted to the EMA in January 2020 for the same indication and the CHMP issued a positive opinion in January 2021. Competition in the MS market is intense. There are numerous FDA-approved drugs for the treatment of the various forms of MS, including Biogen Inc.'s Tecfidera®, Novartis' GILENYA®, Sanofi's AUBAGIO® and several mAbs such as Genentech's OCREVUS® (a CD20 antibody), Sanofi's LEMTRADA® and Biogen's TYSABRI®; glatiramer acetate-based therapies such as Teva Pharmaceutical Industries Limited's COPAXONE® and Sandoz's Glatopa®; and interferon-beta-based therapies such as Biogen's AVONEX® and PLEGRIDY®, Bayer AG's BETASERON®/Betaferon®, Novartis' EXTAVIA®, and Merck KGaA's Rebif®. A number of companies are also working to develop additional potential treatments for MS that may in the future further intensify the competition in the MS market, such as Celgene's Ozanimod and Novartis' Siponimod, which are currently being evaluated in Phase III clinical trials. Potential future sales may also be negatively impacted by the introduction of generics, prodrugs of existing therapeutics or biosimilars of existing products and other technologies.

With respect to tisotumab vedotin, we are aware of other companies that currently have products in development for the treatment of late-stage cervical cancer, which could be competitive with tisotumab vedotin, including checkpoint inhibitors from Agenus Inc., Regeneron Pharmaceuticals Inc., BMS, Merck, Roche, and Innovent Biologics, Inc. as well as other drugs in development from companies such as Immunomedics. Additionally lifileucel (LN-145, autologous tumor infiltrating lymphocytes ("TIL") therapy) from Iovance is in a Phase II study for recurrent, metastatic or persistent cervical carcinoma with a regulatory filing anticipated in 2021.

We are similarly aware, with respect to epcoritamab, of a number of other companies that have bispecific CD3xCD20-targeted product candidates in development for the treatment of B-cell malignancies, which could be competitive with epcoritamab including Regeneron's odronextamab, Roche's mosunetuzumab, which has BTD and for which a regulatory filing is anticipated in 2021, and glofitamab, Xencor's plamotamab and IGM biosciences IGM 2323. We are also aware that there are a number of various CD20 and CD19 antibodies, immunomodulators, ADCs, tyrosine kinase inhibitors and CAR-T therapies that are either approved or in development for non-Hodgkin's lymphomas.

With respect to DuoBody-PD-L1x4-1BB, we are aware of a number of other companies that have bispecific PD-L1x4-1BB products in development for the treatment of solid cancers including Merus and Incyte's MCLA-145, Elpiscience and Inhibrix's INBRX-105, Numab and Cstone Pharmaceuticals NM21-1480, Pieris's PRS-344, F-Star's FS222 and Macrogenics's PD-L1xCD137 DART.

In addition, many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our products and product candidates are designed and being developed to treat. We are also aware of other companies that have or are developing technologies that may be competitive with ours, including bispecific antibody, CAR-T and RNA-based technologies. In addition, our DuoBody and other technology partners may develop compounds utilizing our technology that may compete with product candidates that we are developing.

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA-approved biological product. This pathway allows competitors to reference the FDA's prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Data exclusivity only assures that another company cannot rely on the FDA's prior approvals in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. In the European Union, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product classspecific guidelines for biosimilar approvals issued since 2005. We are aware of many pharmaceutical and biotechnology companies, as well as other companies that are actively engaged in research and development of biosimilars or interchangeable products.

It is possible that our competitors will succeed in developing technologies that are more effective than our products or our product candidates or that would render our technology obsolete or noncompetitive or will succeed in developing biosimilar or interchangeable products for our products or our product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of our products or our product candidates.

With respect to our current and potential future product candidates, we believe that our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- advance our products, product candidates and technology platforms;
- license or acquire additional technology;
- complete clinical trials which position our products for regulatory and commercial success;
- maintain a proprietary position in our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;
- establish efficient manufacturing processes and supply chain;

- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to our business, including the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional collaborations to advance the development and commercialization of our product candidates.

#### **Product and Technology Collaborations**

#### **Collaborations for our Marketed Products**

Janssen Daratumumab License and Development Agreement

In August 2012, we entered into a global license, development and commercialization agreement with Janssen Biotech Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Janssen, granting Janssen an exclusive, sublicensable license to certain of our patents, know-how and materials, owned by or licensed to us, to research, develop, make, offer and sell worldwide certain licensed products containing the human mAb denoted "daratumumab," also known as HuMax-CD38 and DARZALEX. With respect to the licensed technology, we have given up the ability to develop or commercialize other products with affinity to the CD38 antigen target. We recorded an upfront license fee of \$55.0 million and Johnson & Johnson Development Corporation invested DKK 475.2 million (approximately \$80.0 million at the date of the agreement) to subscribe for 5.4 million newly issued shares of Genmab at a price of DKK 88 per share. Janssen is fully responsible for developing and commercializing the licensed products and all costs associated therewith.

Under this agreement, we could be entitled to up to approximately \$1,015 million in development, regulatory and sales milestones, in addition to tiered double-digit royalties between 12% and 20% of net sales. As of December 31, 2020, Genmab has recorded \$850 million in milestone payments from Janssen and could be entitled to receive up to \$165 million in further payments if certain additional milestones are met. In 2019, sales milestones of \$100 million and \$150 million upon net sales reaching \$2.5 billion and \$3.0 billion in a calendar year, as calculated on the basis of the license agreement terms, were achieved. No further sales milestones are due under the license agreement. The following royalty tiers apply for net sales in a calendar year: 12% on net sales up to and including \$750 million; 13% on net sales above \$750 million and up to and including \$1.5 billion; 16% on net sales above \$1.5 billion and up to and including \$2.0 billion; 18% on net sales above \$2.0 billion and up to and including \$3.0 billion; and 20% on net sales exceeding \$3.0 billion. The royalties payable by Janssen are limited in time and subject to reduction on a country-by-country basis for customary reduction events, including upon patent expiration or invalidation in the relevant country and upon the first commercial sale of a biosimilar product in the relevant country (for as long as the biosimilar product remains for sale in that country). Pursuant to the terms of the agreement, Janssen's obligation to pay royalties under this agreement will expire on a country-bycountry basis on the later of the date that is 13 years after the first sale of daratumumab in such country or upon the expiration of the last-to-expire relevant product patent (as defined in the agreement) covering daratumumab in such country. Our issued U.S., European and Japanese patents covering the composition of matter for daratumumab do not begin to expire until March 2026. Janssen may fully or partially terminate the agreement at any time upon 150 days' prior written notice to us. Upon Janssen's termination of the agreement, we are granted an exclusive, perpetual, sublicensable license under any intellectual property controlled by Janssen or its affiliates to the extent necessary to make, have made, import, use, offer to sell or sell the terminated licensed product in such territory where the license has been terminated. If certain milestones have been met by Janssen prior to the termination, then we must pay royalties to Janssen for 10 years from our first commercial sale of a licensed product. In September 2020, Genmab commenced binding arbitration of two matters arising under the license agreement with Janssen relating to daratumumab. The arbitration is to settle whether Genmab is required to share in Janssen's royalty payments to Halozyme for the Halozyme enzyme technology used in the SubQ formulation of daratumumab and whether Janssen's obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-toexpire relevant Janssen-owned patent covering daratumumab.

### Novartis Ofatumumab Collaboration

In December 2006, we entered into a co-development and collaboration agreement with GlaxoSmithKline ("GSK"), pursuant to which GSK obtained exclusive, worldwide rights to develop and commercialize of atumumab. This agreement was subsequently amended in 2010. In 2015, GSK transferred the ofatumumab collaboration for oncology and autoimmune diseases to Novartis. Novartis is now responsible for the development and commercialization of ofatumumab in all potential indications. Novartis is fully responsible for all costs associated with developing and commercializing ofatumumab. Under the current agreement with Novartis, we are entitled to royalties of 20% of worldwide net sales of ofatumumab for intravenous treatments and 10% of worldwide net sales of ofatumumab for non-intravenous treatments, as well as certain potential regulatory and sales milestones, of which only certain sales milestones remain. Ofatumumab is approved in Japan under the name Arzerra for the treatment of certain CLL cancer indications, where of atumumab is being administered intravenously. In addition, Novartis is currently investigating a subQ formulation of ofatumumab for the treatment of RMS and has obtained approval for this indication in the US in August 2020. We therefore believe that the split between intravenous and non-intravenous administration of ofatumumab will, in practice, align with the split between cancer and non-cancer treatments, and we therefore generally refer to the higher royalty rate as being applicable to cancer treatments and the lower royalty rate as being applicable to non-cancer treatments. The royalties are on a country-bycountry basis subject to reduction in a specified amount based on the market share of competing products or a joint committee determination that a license of intellectual property owned by a third party is necessary for commercialization. Novartis can terminate the agreement in its entirety or on a country-by-country basis at any time on nine months' prior written notice. In January 2018, due to low and decreasing global demand for Arzerra primarily related to increased competition from new entrants to the CLL treatment space, Novartis announced that it would transition the commercial availability of Arzerra to limited availability through managed access programs or alternative solutions for the treatment of approved CLL indications in non-U.S. markets where applicable and allowed by local regulations. In 2019, marketing authorizations for Arzerra were withdrawn in the European Union and certain other territories. In August 2020, Genmab announced that Novartis planned to transition Arzerra to an oncology access program for CLL patients in the U.S. Genmab recognized \$30 million lump sum from Novartis as payment for lost potential royalties. Ofatumumab is no longer in development for CLL. Arzerra remains commercially available for approved CLL indications in Japan. Also in August 2020, the FDA approved the use of Kesimpta injection for SubQ use, for the treatment of RMS in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. This followed an sBLA submitted by Novartis in February 2020, which was accepted by the FDA with priority review. At the end of January 2020, an MAA was accepted by the EMA. Subsequently the CHMP issued a positive opinion in January 2021. In July 2020, Novartis submitted an application for approval in this indication in Japan.

# Roche / Horizon Teprotumumab Collaboration

In May 2001, Genmab entered a collaboration with Roche to develop human antibodies to disease targets identified by Roche. In 2002, this alliance was expanded, and Roche made an equity investment in Genmab. Under the agreement, Genmab will receive milestones as well as royalty payments on successful products and, in certain circumstances, Genmab could obtain rights to develop products based on disease targets identified by Roche. Teprotumumab was created by Genmab under the collaboration with Roche and development and commercialization of the product, which was approved in 2020 by the U.S. FDA, as TEPEZZA, for the treatment of thyroid eye disease, is now being conducted by Horizon Therapeutics under a license from Roche. Under the terms of Genmab's agreement with Roche, Genmab will receive midsingle digit royalties on sales of TEPEZZA.

## Certain Collaborations for our Proprietary Product Candidates

### AbbVie Collaboration Agreement

In June 2020, we entered into a Collaboration and License Agreement with AbbVie Biotechnology Ltd., or AbbVie, to jointly develop and commercialize three of our early-stage investigational bispecific antibody product candidates. In addition, under the agreement, we agreed with AbbVie to enter into a discovery research collaboration for future differentiated antibody therapeutics for cancer. The joint development efforts involve our three bispecific antibody programs epcoritamab (DuoBody®-CD3xCD20), DuoHexaBody®-CD37 and DuoBody-CD3x5T4.

For epcoritamab, we share commercial responsibilities with AbbVie in the United States and Japan, while AbbVie is responsible for global commercialization outside of the United States and Japan. We will book net sales of epcoritamab in the United States and Japan and receive tiered royalties on remaining global sales. For DuoHexaBody-CD37, DuoBody-CD3x5T4 and any product candidates developed as a result of the discovery research collaboration, we will share responsibilities with AbbVie for global development and commercialization in the United States and Japan. Subject to certain requirements, we have an option to co-commercialize these products, along with AbbVie, outside of the United States and Japan.

We and AbbVie grant to each other co-exclusive licenses to use certain intellectual property that is necessary for or directly related to the development, manufacture or commercialization of the compounds being developed under the agreement and the resulting licensed products, as further described in the agreement. The licenses can be sublicensed to affiliates of the applicable licensee or to third party sub-contractors meeting certain requirements or if otherwise approved.

Under the terms of the agreement, we received a \$750 million upfront payment in June 2020 and we may be entitled to receive an aggregate of up to \$3.15 billion in additional development, regulatory and sales milestone payments for all programs. Included in these potential milestones are up to \$1.15 billion in payments related to clinical development and commercial success across the three existing bispecific antibody programs. In addition, after we enter into the discovery research collaboration, we are eligible to receive up to \$2.0 billion in option exercise and success-based milestone payments under this agreement and the discovery research collaboration agreement if all four next-generation antibody product candidates developed as a result of the discovery research collaboration are successful. We are further entitled to tiered royalties between 22% and 26% on net sales for epcoritamab outside the United States and Japan. Except for these royalty-bearing sales, we will share with AbbVie pre-tax profits from the sale of licensed products on a 50:50 basis.

The agreement expires when neither we nor AbbVie are developing or commercializing any licensed products. AbbVie may terminate the agreement at AbbVie's convenience at any time after a certain notice period, either in whole or on a licensed product-by-licensed product basis or on a region-by-region basis. The United States and Japan as a whole, Europe as a whole, and the rest of the world each constitute one region for this purpose. If we or AbbVie terminate the agreement due to a material breach, insolvency event or force majeure event with respect to the other party, the terminating party will have the exclusive right (including the exclusive right to use the intellectual property licensed to it under the agreement) to develop, manufacture and commercialize the terminated licensed product in the terminated region. The terminating party will pay the other party a royalty on net sales of the terminated product in the terminated region up to certain thresholds depending on which party terminated the agreement. A termination by AbbVie for convenience is treated the same way as a termination by Genmab for a material breach by AbbVie for this purpose, which means that Genmab would have the exclusive right to develop, manufacture and commercialize the terminated licensed product in the terminated region.

### Seagen Tisotumab Vedotin Collaboration

In October 2011, we entered into a license and collaboration agreement with Seagen granting us an exclusive right to utilize Seagen's ADC technology with our HuMax-TF antibody in return for milestone payments and royalties. We also granted Seagen a right to exercise a co-development and co-commercialization option at the end of Phase I clinical development for tisotumab vedotin. In August 2017, Seagen exercised this option to co-develop and co-commercialize tisotumab vedotin with us. Under our collaboration agreement, Seagen and Genmab will each be responsible for leading commercialization activities in certain territories. In October 2020, Genmab and Seagen entered into a joint commercialization agreement. Genmab will co-promote tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. In all other markets, if any, Seagen will be responsible for commercializing tisotumab vedotin and Genmab will receive royalties based on a percentage of aggregate net sales ranging from the mid-teens to the mid-twenties. The companies will continue the practice of joint decision-making on the worldwide development and commercialization strategy for tisotumab vedotin.

#### BioNTech DuoBody Collaboration

In May 2015, we entered into an agreement with BioNTech SE, or BioNTech to jointly research, develop and commercialize bispecific antibody products using our DuoBody technology platform and antibodies. Under the terms of the agreement, BioNTech provides proprietary antibodies against key immunomodulatory targets, while we provide access to our DuoBody technology platform. We paid an upfront fee of \$10 million to BioNTech and an additional \$2 million as certain BioNTech assets were selected for further development. If the companies jointly select any product candidates for clinical development, development costs and product ownership will be shared equally going forward. If one of the companies does not wish to move a product candidate forward, the other company is entitled to continue developing the product on predetermined licensing terms. The agreement also includes provisions which will allow the parties to opt out of joint development at key points. Two product candidates are currently in clinical development in connection with this agreement, DuoBody-PD-L1x4-1BB and DuoBody-CD40x4-1BB.

### Seagen ADC Technology License

In September 2014, we entered into an ADC license agreement with Seagen. Under this agreement, we paid an upfront fee of \$11 million for exclusive rights to utilize Seagen's ADC technology with our HuMax-AXL antibody. Pursuant to this agreement, Seagen is also entitled to receive more than \$200 million in potential milestone payments and mid-to-high single digit royalties on worldwide net sales of any resulting products. In addition, prior to our initiation of a Phase III study for any resulting products, Seagen has the right to exercise an option to increase the royalties to the low tens in exchange for a reduction of the milestone payments owed by us. Irrespective of any exercise of this option, we remain in full control of the development and commercialization of any resulting products.

In November 2020 we announced that we would not advance the development of enapotamab vedotin.

### Certain other Collaborations, Agreements and Enabling Technologies

Medarex UltiMAb® System License

In 1999, we entered into a license agreement with Medarex, now a wholly-owned subsidiary of BMS, pursuant to which we received access to the UltiMAb technology, the KM Mouse technology and the right to obtain antibodyexclusive licenses for an unlimited number of antigens and own the worldwide development and commercialization rights to antibody products targeting such antigens. In addition, Medarex granted us 16 antigen-exclusive licenses in exchange for Genmab shares that are fully paid-up subject to, in case the products have been generated in the KM Mouse, pass-through of milestones and royalties payable by Medarex under its own license of the KM Mouse technology. Our principal obligation under this agreement is to make milestone and royalty payments in connection with any such antibody-exclusive licenses or in connection with use of the KM Mouse technology under this agreement. We used technology licensed from Medarex to generate daratumumab, ofatumumab, tisotumab, forming part of tisotumab vedotin, enapotamab, forming part of enapotamab vedotin, the CD20 antibody forming part of epcoritamab (DuoBody-CD3xCD20), and certain of our other product candidates. Based on the type of license and technology used in their development, product candidates that are subject to future payment obligations under this license agreement include of atumumab, enapotamab vedotin, epcoritamab (DuoBody-CD3-CD20), DuoBody-cMetxEGFR and Lu AF82422, but do not include daratumumab, tisotumab vedotin and HexaBody-CD38. With respect to ofatumumab and Lu AF82422, Novartis and Lundbeck, respectively, have agreed to bear the majority of our payments to Medarex under these agreements. Aggregate milestones for the product candidates subject to payment obligations range from \$1.5 million to \$6 million per product, of which a total of approximately \$17.4 million remains payable by us or our partners across all such product candidates currently in development. Royalties are in the low single digits of net sales.

# Janssen HexaBody-CD38 Collaboration

In June 2019, we entered into an exclusive worldwide license and option agreement with Janssen to develop and commercialize HexaBody-CD38, a next-generation human CD38 mAb product incorporating our proprietary HexaBody technology. Under the terms of the agreement, we have agreed to collaborate exclusively with Janssen on HexaBody-CD38 and to fund research and development activities until completion of clinical proof of concept studies in

MM and DLBCL. Based on the data from these studies, Janssen may exercise its option and receive a worldwide exclusive license to certain of our intellectual property and an exclusive sublicense to certain intellectual property that we license from third parties, in each case, to develop, manufacture and commercialize HexaBody-CD38. If Janssen exercises this option, we will be entitled to a \$150 million option exercise fee and up to \$125 million in development milestones, as well as a flat royalty rate of 20% on sales of HexaBody-CD38 until a specified time in 2031, followed by 13-20% tiered royalties on sales thereafter. Upon exercising the option, Janssen will be entitled to terminate the agreement in its entirety or on a country-by-country basis for any reason with 150 days prior written notice to us. Should Janssen not exercise its option, the agreement will terminate, and we may unilaterally continue to develop and commercialize HexaBody-CD38 for daratumumab-resistant patients, and in all other indications except those MM or amyloidosis indications where daratumumab is either approved or is being actively developed. The IND for HexaBody-CD38 was submitted to the FDA in October 2020 and the first CTA, in Denmark, was submitted in November 2020. The first patient was dosed with HexaBody-CD38 in March 2021.

### Other Collaborations and Agreements

We have other active collaborations and agreements with a number of companies, including Janssen, ADC Therapeutics, BMS, Lundbeck, Amgen, Immatics, Novo Nordisk, CureVac and Tempus to create, develop and/or commercialize antibody candidates and/or license certain of our product candidates and use of our technology platforms. Under these collaborations and agreements, which we have entered into in the ordinary course of business, and where we have licensed our product candidates or technology platforms, we typically receive or are entitled to receive upfront cash payments, progress- and sales-dependent milestones for the achievement by our collaborators of certain events, and, where applicable, research funding. We also are entitled to receive royalties on net sales of commercialized products resulting from the collaborations.

We also license technologies from a number of other companies that we use or have used to contribute to the antibody products in our pipeline. Key technologies include Seagen's ADC technologies, the OmniAb transgenic mouse and rat platforms from Open Monoclonal Technology, Inc., certain transgenic mouse technologies from Medarex, the rabbit antibody platform from MAB Discovery GmbH and certain expression systems used by Lonza for production of our product candidates. Pursuant to certain of these licenses, we or our partners are or may be obligated to pay small royalties for certain products generated or produced using these technologies upon commercialization of such products or product candidates. We also license certain targets disclosed and developed from Immatics' XPRESIDENT targets and T-cell receptor technology as part a research collaboration and exclusive license agreement with Immatics to discover and develop next-generation bispecific immunotherapies to target multiple cancer indications. As part of this collaboration, Immatics is or may be eligible to receive certain milestone payments and tiered royalties on net sales. We also entered into a research collaboration and license agreement with CureVac AG focusing on the research and development of differentiated mRNA-based antibody products by combining CureVac's mRNA technology and know-how with Genmab's proprietary antibody technologies and expertise. As part of this agreement CureVac is or may be eligible to receive certain milestone payments and tiered royalties on net sales.

### **Intellectual Property**

## **Patents**

As of March 1, 2021, we held more than 1,900 patents and patent applications, including more than 55 issued U.S. patents and more than 80 U.S. patent applications. All of our current issued patents and patent applications are projected to expire between 2021 and 2040.

Our owned and licensed patents and patent applications are directed to daratumumab, ofatumumab, our product candidates, antibodies, our proprietary technologies and other antibody-based and/or enabling technologies. We commonly seek patent claims directed to compositions of matter, including antibodies, bispecific antibodies, and antibody drug conjugates, as well as methods of using such compositions. When appropriate, we also seek claims to related technologies, such as antibody format technologies. For daratumumab, ofatumumab and each of our product candidates, we or our partners have filed or expect to file multiple patent applications. We maintain patents and prosecute applications worldwide for technologies that we have out-licensed, such as our DuoBody technology.

Similarly, for partnered products and product candidates, such as daratumumab, ofatumumab and tisotumab vedotin, we seek to work closely with our development partners to coordinate patent efforts, including patent application filings, prosecution, patent term extension, defense and enforcement. As daratumumab, ofatumumab, teprotumumab and our development product candidates advance through research and development, we seek to diligently identify and protect new inventions, such as formulations, combination therapies, and methods of treatment. We also work closely with our scientific personnel to identify and protect new inventions that could eventually add to our development or technology pipeline.

With respect to daratumumab, we have issued patents and pending patent applications in numerous jurisdictions, including patents issued in the United States, Europe and Japan. Our issued U.S., European and Japanese patents covering the composition of matter for daratumumab do not begin to expire until March 2026. In addition to our key composition of matter patents for daratumumab, we and Janssen have issued patents and pending patent applications in numerous jurisdictions and for specific formulations, indications and combination therapies that may offer additional protection. With respect to ofatumumab, we have issued patents and pending patent applications in numerous jurisdictions, including in the United States, Europe and Japan. Our issued U.S., European and Japanese patents covering the composition of matter for ofatumumab do not begin to expire until October 2023, with the U.S. composition of matter patent extended to May 2031. Novartis has issued patents and pending patent applications in numerous jurisdictions, including the United States, Europe and Japan. Our issued U.S., European and Japanese patents covering the composition of matter for tisotumab vedotin, we have issued patents and pending patent applications in numerous jurisdictions relating to specific formulations, indications and combination therapies that may offer additional protection.

The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage as determined by the patent office or courts in the country, and the availability of legal remedies in the country. This list above does not identify all patents that may be related to daratumumab, ofatumumab and our product candidates. For example, in addition to the listed patents, we have patents on platform technologies (that relate to certain general classes of products or methods), as well as patents that relate to methods of using, formulating or administering a product or product candidate, which may confer additional patent protection. We also have pending patent applications that may give rise to new patents related to one or more of these product candidates, technologies, formulations and uses.

The information in the above list is based on our current assessment of patents that we own or control or have exclusively licensed. The information is subject to revision, for example, in the event of changes in the law or legal rulings affecting our patents or if we become aware of new information. Significant legal issues remain unresolved as to the extent and scope of available patent protection for biotechnology products and processes in the United States and other important markets outside the United States. We expect that litigation will likely be necessary to determine the term, validity, enforceability, and/or scope of certain of our patents and other proprietary rights. An adverse decision or ruling with respect to one or more of our patents could result in the loss of patent protection for a product and, in turn, the introduction of competitor products or follow-on biologics to the market earlier than anticipated.

Patents expire, on a country-by-country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term adjustment, patent term extension and supplemental protection certificates and requirements for terminal disclaimers. Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our partners may not be able to develop patentable products or processes or obtain patents from pending patent applications. In the event of patent issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our partners. Our or our partners' current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. In addition, changes to patent laws in the United States or in other countries may limit our ability to defend or enforce our patents, or may apply retroactively to affect the term and/or scope of our patents. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid, not infringed or unenforceable under U.S. or foreign laws, or they may be

infringed by third parties. As a result, we are or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law and administrative tribunals, such as in USPTO inter partes review or reexamination proceedings, foreign opposition proceedings or related legal and administrative proceedings in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings or litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our partners' patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our partners.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. Organizations such as pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned or licensed to us or to our partners. In addition, we are monitoring the progress of several pending patent applications of other organizations that, if granted in their broadest scope, may require us to license or challenge their validity or enforceability in order to continue commercializing our products and product candidates directly or through our partners. Our and our partners' challenges to patents of other organizations may not be successful, which may affect our and our partners' ability to commercialize daratumumab, ofatumumab or teprotumumab or our ability to commercialize our product candidates. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our partners' ability to make, use or sell daratumumab, ofatumumab, teprotumumab or any other products or product candidates.

#### **Trademarks**

As of April 17, 2019, we and/or our subsidiaries own approximately 285 international trademark registrations and applications, and 12 U.S. trademark registrations, including: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; DuoBody®; DuoBody®; DuoBody in combination with the DuoBody logo®; HexaBody®; HexaBody in combination with the HexaBody logo®; DuoHexaBody®; HexElect®; and UniBody®. Arzerra® is a trademark of Novartis Pharma AG. Kesimpta® is a trademark of Novartis Pharma AG or its affiliates. DARZALEX® and DARZALEX FASPRO® are trademarks of Johnson & Johnson. TEPEZZA® is a trademark of Horizon Therapeutics Ireland DAC. Other than the registered trademarks listed above, we currently rely on our unregistered trademarks, trade names and service marks, as well as our domain names and logos, as appropriate, to market our brands and to build and maintain brand recognition. We are seeking to register and will continue to seek to register and renew, or secure by contract where appropriate, trademarks, trade names and service marks as they are developed and used, and reserve, register and renew domain names as appropriate. If we do not secure trademark registration successfully for our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our rights in our trademarks, trade names and service marks against third parties.

### **Trade Secrets**

We require our scientific personnel to maintain laboratory notebooks and other research records in accordance with our policies, which are also designed to strengthen and support our intellectual property protection. In addition to our patented intellectual property, we also rely on trade secrets and other proprietary information, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a proprietary information and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we will own all inventions conceived or reduced to practice by the individual in the course of rendering services to us. Our agreements with partners require them to have a similar policy and agreements with their employees, consultants and advisors to ensure the agreed upon allotment of intellectual property rights can be enforced. Our policy and agreements and those of our partners may not sufficiently protect our confidential information, or third parties may independently develop equivalent information.

#### **Government Regulation**

The FDA, the EMA and other regulatory authorities at U.S. federal, state, and local levels, as well as in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with our partners and third-party contractors, are required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and financial resources. The following sections outline the approval process and other rules and regulations applicable to biologics in the United States and the European Union. While the regulatory process in many countries is similar to the United States or the European Union, each jurisdiction has its own regulations, and approval in one jurisdiction does not guarantee approval in any other jurisdiction.

#### Review and Approval of Biologic Products in the United States

Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and other federal, state, local and foreign statutes and regulations. Our product candidates must be approved by the FDA before they may be legally marketed in the United States.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices (cGLPs) regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be
  updated annually or when significant changes are made;
- approval by an independent Institutional Review Board ("IRB"), or ethics committee at each clinical site before the trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which
  the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods
  and controls are adequate to preserve the biological product's continued safety, purity and potency, and of
  selected clinical investigations to assess compliance with current cGCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated annually when significant changes are made.

Prior to beginning the first clinical trial with a product candidate in the United States, we or our partner must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug

product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

A clinical trial involves the administration of the investigational product to human patients under the supervision of qualified investigators in accordance with cGCPs, which includes the requirement that all research patients provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or data monitoring committee, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for patients or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase I—The investigational product is initially introduced into human patients with the target disease or
  condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and
  distribution of the investigational product in humans, the side effects associated with increasing doses, and, if
  possible, to gain early evidence on effectiveness.
- Phase II—The investigational product is administered to a limited patient population with a specified disease
  or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify
  possible adverse side effects and safety risks. Multiple Phase II clinical trials may be conducted to obtain
  information prior to beginning larger and more expensive Phase III clinical trials and we often we conduct
  Phase I/II studies. Some of the Phase II studies can potentially provide an adequate basis for regulatory
  approval.
- Phase III—The investigational product is administered to an expanded patient population to further evaluate
  dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally
  at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the
  overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase IV studies may be made a condition to approval of the BLA.

Phase I, Phase II and Phase III testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with

clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, non-clinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent pre-clinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is also subject to annual program fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act ("**PREA**"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan within sixty days after an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Once a BLA has been submitted, the FDA's goal is to review the application within 10 months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process may be extended by the FDA's requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us or our partners from marketing our products. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the product will be produced, the FDA may issue an approval, which authorizes commercial marketing of the product with specific prescribing information for specific indications or either a Refuse to File notice or a Complete Response Letter. A Refuse to File notice indicates the areas in which the BLA is incomplete or if there are issues with the content or format of the application. A Complete Response Letter indicates that the review

cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase IV post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

#### **Expedited Development and Review Programs**

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation, or FTD, if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address an unmet medical need for the condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. An FTD product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical objective that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, a sponsor may seek FDA breakthrough therapy designation, or BTD, of its product candidate if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant objectives, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-Phase II meeting with the FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of

patients exposed to a potentially less efficacious treatment. BTD also allows the sponsor to submit sections of the BLA for review on a rolling basis.

The FDA is also exploring other options to expedite processing of certain applications. For example, in 2018 the FDA started using real-time review of drug applications to evaluate clinical data as soon as the trial results become available. This means that the FDA can approve a new indication soon after an applicant files a marketing application. Currently, this approach is only being implemented by the FDA's Oncology Center of Excellence through two pilot programs, including the FDA's RTOR Pilot Program, which is currently available for certain supplemental applications for already-approved cancer drugs.

FTD, priority review, BTD, and pilot review programs do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

#### **Review and Approval of Combination Products**

Although most of our product candidates are regulated as biologics, certain of our product candidates are subject to regulation in the United States as combination products. If marketed individually, each component would be subject to different regulatory pathways and would require FDA approval of independent marketing applications by the FDA. A combination product, however, is assigned to a Center within the FDA that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. Our ADC candidates are both drug and biologic molecules. Such ADCs are regulated as therapeutic biologics and the FDA's Center for Drug Evaluation and Research ("CDER"), will have primary jurisdiction over pre-market development. The CDER currently has regulatory responsibility, including premarket review and continuing oversight, over certain therapeutic biologic products. We expect to seek approval of these combination products through single BLA reviewed by CDER, and we do not expect that the FDA will require a separate marketing authorization for each of the drug and biologic constituents of such products.

#### **Post-Approval Requirements**

Any products manufactured or distributed by us or our partners pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we or our partners may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us or our partners to recall a product from distribution, or withdraw approval of the BLA.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products and product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including

withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of any off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict marketing authorization holders' communications on the subject of off-label use of their products.

### Biosimilars and Exclusivity

The Affordable Care Act, signed into law in 2010, includes the BPCIA subtitle, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or diminishing efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the

reference product if the FDA approves a full BLA for the competing product containing that applicant's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact of the BPCIA is subject to significant uncertainty.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

### Regulation of Diagnostic Tests

Certain of our product candidates may require use of a diagnostic to identify appropriate patient populations that may benefit from our products. These companion diagnostics are medical devices, often *in vitro* devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the United States, unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and approval of a premarket approval application ("**PMA**") approval. We expect that any companion diagnostic developed for our drug candidates will utilize the PMA pathway.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, pre-clinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data is submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, for novel drugs such as ours, a companion diagnostic device and its corresponding drug should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption ("IDE"), regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations.

In the EEA, *in vitro* diagnostics medical devices are required to conform with the essential requirements of the EU Directive on *in vitro* diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of *in vitro* diagnostics medical device and its classification. The conformity assessment of *in vitro* diagnostics medical devices can require the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA.

On April 5, 2017, the European Parliament passed the In Vitro Device Regulation ("**IVDR**"), which repeals and replaces Directive No 98/79/EC. Unlike directives, which must be implemented into the national laws of the EU member states, a regulation is directly applicable, i.e., without the need for adoption of EU member state laws implementing them, in all EEA member states. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for *in vitro* diagnostic medical devices and ensure a high level of safety and health while supporting innovation. The IVDR will not become fully applicable until five years following its entry into force.

#### Other Healthcare Laws and Compliance Requirements

Healthcare providers and third-party payers play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payers and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or a specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to \$100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary
  penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or
  causing to be presented, to the federal government, claims for payment that are false or fraudulent or making
  a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When
  an entity is determined to have violated the federal civil False Claims Act, the government may impose civil
  fines and penalties and exclude the entity from participation in Medicare, Medicaid and other federal
  healthcare programs;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and
  willingly executing, or attempting to execute, a scheme or making false statements in connection with the
  delivery of or payment for health care benefits, items, or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its
  implementing regulations, which also imposes obligations, including mandatory contractual terms, with
  respect to safeguarding the privacy, security and transmission of individually identifiable health information
  on covered entities and their business associates that perform certain functions or activities that involve the
  use or disclosure of protected health information on their behalf. Similar to the federal Anti-Kickback Statute,
  a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have
  committed a violation;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals and information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which
  may apply to healthcare items or services that are reimbursed by non-governmental third-party payers,
  including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

### Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer
   Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability; and

 a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of two percent (2%) per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.

Since its enactment, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the ACA. Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, former President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Moreover, the Tax Reform Bill was enacted on December 22, 2017, and includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace additional elements of the ACA. We continue to evaluate the effect that the ACA, the repeal of the individual mandate, and any additional repeal and replacement efforts may have on our business but expect that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our product candidates, if approved. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to keep healthcare costs down while expanding individual healthcare benefits.

#### **Coverage and Reimbursement**

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payers include government health administrative authorities, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payers will provide coverage and reimbursement for our products and product candidates, if approved, these third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time-consuming and expensive for us to seek coverage and reimbursement from third-party payers. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The process for determining whether a payer will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payer will pay for the product. A payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payers for coverage or reimbursement. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. One third-party payer's decision to cover a particular medical product or service does not ensure that other payers will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately and will likely be a time-consuming process. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payers may not consider our products or product candidates to be medically necessary or cost-effective compared to other available therapies.

Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payers do not consider our products to be cost-effective compared to other therapies, they may not cover our products or product candidates once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payer not to cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressures or reduced demand for our products or product candidates once approved.

#### Review and Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pre-clinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on Good Clinical Practice and the related national implementing provisions of the individual EU member states ("EU Member States"), govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the Clinical Trials Regulation, (EU) No 536/2014 ("Clinical Trials Regulation") was adopted. Timing of its application will depend on confirmation of full functionality of the Clinical Trials Information System via independent audit. The Clinical Trials Regulation will become applicable six months after the European Commission publishes notice of this confirmation. The Clinical Trials Regulation will be directly applicable in all of the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trials regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (EU Member States concerned). Part II is assessed separately by each EU Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

To obtain a marketing authorization for a product under European Union regulatory systems, an applicant must submit an MAA either under a centralized procedure administered by the EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU Member States and three of the four European Free Trade Association States, Iceland, Liechtenstein and Norway. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several postauthorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 15 calendar days of receipt of a final opinion from the CHMP, the European Commission must prepare a draft decision concerning an application for marketing authorization. This draft decision must take the opinion and any relevant provisions of EU law into account. Before arriving at a final decision on an application for centralized authorization of a medicinal product the European Commission must consult the Standing Committee on Medicinal Products for Human Use (the "Standing Committee"). The Standing Committee is composed of representatives of the EU Member States and chaired by a non-voting European Commission representative. The European Parliament also has a related "droit de regard". The European Parliament's role is to ensure that the European Commission has not exceeded its powers in deciding to grant or refuse to grant a marketing authorization.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment

report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

In the European Union, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance with the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics of these innovative products from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic medicinal product can be placed on the European Union market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, pre-clinical tests and clinical trials.

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the European Union market (in case of centralized procedure) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a drug can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Once authorized, orphan medicinal products are entitled to 10 years of market exclusivity in all EU Member States and in addition a range of other benefits during the development and regulatory review process including scientific assistance for study protocols, authorization through the centralized marketing authorization procedure covering all member countries and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer

of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of the 10 years of market exclusivity.

In case an authorization for a medicinal product in the European Union is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the European Union's stringent pharmacovigilance or safety reporting rules must be
  ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with European Union cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union.
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical
  education and advertising directed toward the prescribers of drugs and/or the general public, are strictly
  regulated in the European Union notably under Directive 2001/83EC, as amended, and EU Member State
  laws.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community and the withdrawal of the United Kingdom from the European Union took place on January 1, 2021. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

### C. ORGANIZATIONAL STRUCTURE

Genmab A/S holds investments either directly or indirectly in the following subsidiaries: Genmab B.V. (Utrecht, the Netherlands), Genmab Holding B.V. (Utrecht, the Netherlands), Genmab US, Inc. (New Jersey, USA) and Genmab K.K. (Tokyo, Japan). The subsidiaries perform certain research & development, general & administrative, and management activities on behalf of Genmab A/S.

### D. PROPERTY, PLANT AND EQUIPMENT

Our corporate headquarters are located in Copenhagen, Denmark, where we currently lease approximately 56,500 square feet, pursuant to a lease agreement dated as of February 15, 2017, by and between us and Castellum 2 i København ApS ("Castellum"), as amended. On December 14, 2018, we entered into an agreement with Castellum for additional lease space in Copenhagen, Denmark, to lease approximately 14,929 square feet. The leases are perpetual, but can be terminated with six months' prior notice, which can be made effective no earlier than December 1, 2022 in the case of termination by us, and no earlier than December 1, 2027 in the case of termination by Castellum. During 2020,

Genmab A/S entered into a lease agreement with respect to the new headquarters in Denmark with a commencement date in March 2023 and is non-cancellable until March 2038.

Our indirectly wholly-owned subsidiary, Genmab B.V., leases approximately 90,094 square feet of office, laboratory and pre-clinical development space in Utrecht, the Netherlands pursuant to a lease agreement dated June 17, 2015. The start date of the lease term is May 22, 2017 and the lease term is 15 years with a cost-free break option at 10 years. Additionally, Genmab B.V. leases approximately 31,591 square feet of office, laboratory and pre-clinical development space in Utrecht, the Netherlands with a termination date of June 30, 2022. During 2019, Genmab B.V. entered into a lease agreement with respect to additional office and laboratory space with a commencement date in February 2022 and is non-cancellable until January 2032.

Our wholly-owned subsidiary, Genmab US, Inc., leases approximately 90,070 square feet of office and laboratory space in Plainsboro, New Jersey with a termination date of August 31, 2031, and leases approximately 24,771 square feet of office space in Princeton, New Jersey with a termination date of December 31, 2022. The Princeton, New Jersey space was subleased in 2020 with a termination date of December 31, 2022. Additionally, Genmab US, Inc. amended a lease agreement for additional office and laboratory space in Plainsboro, New Jersey with a commencement date in April 2021 and is non-cancellable until August 2031.

See Note 3.3 "Leases" in our Audited Financial Statements for additional details regarding the leases.

#### ITEM 4A UNRESOLVED STAFF COMMENTS

Not applicable.

#### ITEM 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

#### A. Operating Results

#### Overview

We are an international biotechnology company specializing in antibody therapeutics for the treatment of cancer and other diseases. Our core purpose is to improve the lives of patients by creating and developing innovative antibody products. Our vision is to transform cancer treatment by launching our own proprietary product by 2025 and advancing our pipeline of differentiated and well-tolerated antibodies. We are building and expanding our late-stage development and commercial capabilities to allow us to bring our proprietary products to market in the future. We are continuing to build a well-diversified portfolio of products, product candidates and technologies. Our portfolio includes three approved partnered products, daratumumab, marketed by Janssen as DARZALEX for the treatment of certain MM indications and, in the U.S., AL amyloidosis, ofatumumab, marketed in the U.S. as Kesimpta by Novartis for the treatment of RMS and teprotumumab, marketed in the U.S. as TEPEZZA, by Horizon for the treatment of TED, in addition to a broad pipeline of differentiated product candidates. Our pipeline includes eight proprietary product candidates in clinical development and approximately 20 proprietary and partnered pre-clinical programs. In addition to our proprietary clinical product candidates and our partners' ongoing label expansion studies for daratumumab, ofatumumab, and teprotumumab, our partners have twelve additional product candidates in clinical development through collaboration agreements with us. Our portfolio also includes four proprietary antibody technologies that play a key role in building our product pipeline, enhancing our partnerships and generating revenue. We selectively enter into collaborations with other biotechnology and pharmaceutical companies that build our network in the biotechnology space and give us access to complementary technologies or products that move us closer to achieving our vision and fulfilling our core purpose.

In addition to our partnered approved products, we are currently building and expanding our commercial capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create value for our shareholders. Our goal is to become a commercial-stage company. Our initial focus will be on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer, subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seagen. Under our agreement, Seagen and Genmab will each be

responsible for leading tisotumab vedotin commercialization activities in certain territories. Under the joint commercial agreement signed in October 2020, Genmab will co-promote tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. In all other markets, if any, Seagen will be responsible for commercializing tisotumab vedotin and Genmab will receive royalties based on a percentage of aggregate net sales ranging from the mid-teens to the mid-twenties. The companies will continue the practice of joint decision-making on the worldwide development and commercialization strategy for tisotumab vedotin.

On June 10, 2020, Genmab entered into a broad collaboration agreement to jointly develop and commercialize epcoritamab, DuoHexaBody-CD37 and DuoBody-CD3x5T4 and a discovery research collaboration for future differentiated antibody therapeutics for cancer. For epcoritamab, the companies will share commercial responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization. Genmab will be the principal for net sales in the U.S. and Japan and receive tiered royalties on remaining global net sales. For DuoHexaBody-CD37, DuoBodyCD3x5T4 and any product candidates developed as a result of the companies' discovery research collaboration, Genmab and AbbVie will share responsibilities for global development and commercialization in the U.S. and Japan. Genmab retains the right to co-commercialize these products, along with AbbVie, outside of the U.S. and Japan. For the discovery research collaboration, Genmab will conduct Phase I studies for these programs and AbbVie retains the right to opt-in to program development.

In 2020, we generated revenue of DKK 10,111 million and recorded operating result of DKK 6,313 million and net result of DKK 4,758 million, as compared to revenue of DKK 5,366 million, operating result of DKK 2,638 million and net result of DKK 2,166 million in 2019. Our results of operations have been, and we expect them to continue to be, affected by our collaboration with Janssen for the development and commercialization of daratumumab. Since inception, we have funded our operating requirements primarily through proceeds from equity financings and milestone payments and royalties from our partners. We expect to continue to fund a significant portion of our development costs for our proprietary product candidates as well as our planned commercialization activities with funds received from royalties and milestone payments from our partners.

For a description of certain of our product and technology collaborations including relevant royalty tiers, milestones and expense sharing provisions, please refer to "Item 4.B—Business Overview—Product and Technology Collaborations" in this Annual Report.

### Key Components of Our Results and Related Trends

## Revenues

Our revenues are currently comprised of royalties, milestone payments, license fees and reimbursement revenue. Royalty income from licenses is based on third-party sales of licensed products. Milestone payments are typically related to reaching particular stages in product development, regulatory approval or net sales. License fees are non-refundable, upfront fees for our intellectual property received from our partners. Reimbursement revenue is mainly comprised of the reimbursement of certain research and development costs related to the development work under our collaboration agreements.

In 2020, DKK 4,693 million, or 46% of our total revenues, related to our various collaborations with Janssen, as compared to DKK 4,983 million, or 93% of our total revenues, in 2019. This decrease was mainly driven by the upfront payment of \$672 million (DKK 4,398 million) related to the AbbVie collaboration that was allocated to license grants and recognized as revenue in June 2020. Excluding the one-time payment from AbbVie, royalties and milestone payments from our various collaborations with Janssen accounted for 82% of our revenue in 2020. In 2020, DKK 4,513 million, or 96% of our revenues received under our various collaborations with Janssen were related to royalties and milestone revenue with respect to DARZALEX, as compared to DKK 4,910 million, or 99% of revenues, in 2019.

Of revenue for 2020, royalties, milestone revenue, license revenue and reimbursement revenue represented 47%, 4%, 45%, and 4%, respectively. The corresponding percentages were 59%, 35%, nil and 6% in 2019. At this time, all of our revenue is recognized from our partners under our collaboration agreements. We do not earn any revenue from direct

sales of our own products, and we will not earn such revenue unless and until we obtain regulatory approvals for any candidates in our proprietary pipeline and successfully commercialize such candidates. Our reported revenue is affected by the translation of royalties and other income denominated in foreign currencies—primarily U.S. dollars—into Danish kroner as our reporting currency.

In addition to existing approvals of DARZALEX for the treatment of certain MM indications in the United States, the European Union, Japan and certain other countries, applications for the SubQ formulation of daratumumab based on the APOLLO and ANDROMEDA studies are currently pending with United States and European regulators or with European and Japanese regulators, respectively. Our ability to generate revenue will significantly depend on the success of Janssen's continued ability to effectively maintain and grow sales of DARZALEX for its approved indications, expand its indications, and successfully compete with existing and additional investigational agents and technologies that are currently being marketed or studied for the same indications as DARZALEX.

Our historical revenue also reflects milestone payments and royalties related to our collaboration with Novartis for ofatumumab, marketed as Arzerra for the treatment of certain indications of CLL, and milestone and other payments relating to our other collaborations. In 2019, the marketing authorization for Arzerra was withdrawn in the EU and several other territories. Subsequently, in August 2020, Genmab announced that Novartis intends to transition availability of Arzerra to an oncology patient access program for CLL patients in the U.S. Arzerra is commercially available in Japan. In August 2020, ofatumumab was approved in the US as Kesimpta for relapsing forms of MS. An MAA in this indication was filed with the EMA in January 2020 and Novartis anticipates approval in Europe in 2021.

We anticipate that our partners under our collaboration agreements will report results or preliminary data for a number of clinical studies in 2021. However, there can be no assurance that any of the studies conducted by Janssen or Novartis or by us or our other partners will be completed on the expected timeline or at all, or that the final results will be positive. Our ability to generate revenue from our partnered product candidates depends on our and our partners' ability to successfully complete clinical trials for our product candidates and receive regulatory approvals, which could impact the commercial potential of such products and our potential to receive milestone payments and royalties for these products in the future.

#### **Operating Expenses**

Our operating expenses currently consist of research and development expenses and general and administrative expenses. Research and development expenses represent the majority of our operating expenses.

Our research and development expenses include internal costs relating to our research and development departments, as well as external costs relating to studies performed by external suppliers and partners. Internal research and development costs consist primarily of salaries and benefits for our research and development staff and related expenses, including expenses related to cash bonuses, warrant and restricted stock unit ("RSU") programs as applicable to such personnel, costs of related facilities, equipment and other overhead expenses that have been determined to be directly attributable to research and development, costs associated with obtaining and maintaining patents for intellectual property, amortization of licenses and rights, amortization and impairment of intangible assets and property, and depreciation of capital assets used to develop our product candidates.

Major components of the external costs are fees and other costs paid to CROs in conjunction with pre-clinical studies and the performance of clinical trials, milestone payments for in-licensed technology, as well as fees paid to CMOs in conjunction with the production of clinical compounds, drug substances and drugs. This includes (i) antibody clinical material for use in clinical trials and (ii) preparation for production of process validation batches for potential future regulatory submissions and related activities. These costs are expensed as incurred, because they do not qualify to be capitalized as inventory under IFRS since the technical feasibility of the materials is not proven and no alternative use for them exists in the absence of marketing approval. Research and development expenses include amortization of intangible assets only in connection with licenses and rights we have acquired and capitalized. We do not capitalize intellectual property generated through our internal development activities. We expect to incur higher research and development costs in future periods, including increasing costs for clinical trials and manufacturing as our proprietary product candidates advance in clinical development and we increase the number of product candidates under active

clinical development. Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including timing due to regulatory approvals and enrollment of patients in clinical trials. See "—Liquidity and Capital Resources" below.

Our general and administrative expenses consist primarily of wages and salaries for personnel other than research and development staff, including expenses related to cash bonuses and warrant and RSU programs as applicable to such personnel. Also included are expenses related to pre-launch commercialization activities, depreciation, amortization and impairment of intangible assets and property, plant and equipment, to the extent such expenses are related to the administrative functions.

Overhead expenses are allocated to research and development expenses or general and administrative expenses based on the number of employees and their relevant functions. The Dutch Research and Development Act ("WBSO"), provides compensation for a part of research and development wages and other costs at our Utrecht facility through a reduction in payroll taxes in the Netherlands. WBSO grant amounts are offset against wages and salaries included in research and development costs.

Our ongoing research and development and, increasingly, pre-launch commercialization activities will require substantial amounts of capital and may not ultimately be successful. Over the next several years, we expect that we will continue to incur substantial expenses, primarily as a result of activities related to the continued development of our proprietary pipeline and building our commercial capabilities. Our proprietary product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and develop into commercially viable products, if they are approved and commercialized at all. Our commitment of resources to the research and continued development of our product candidates and expansion of our proprietary pipeline will likely result in our operating expenses increasing and/or fluctuating as a result of such activities in future periods. We may also incur significant milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

### Potential Impact of COVID-19

The full extent and nature of the impact of the COVID-19 pandemic and related containment measures on our business and financial performance is uncertain as the situation continues to develop. See "Item 3.D—Risk Factors—Risks Related to Our Business—The COVID-19 pandemic could materially adversely impact our business and financial performance, including our clinical trials, projected regulatory approval timelines, supply chain and revenues."

## **Results of Operations**

Financial Results for the Year Ended December 31, 2020 Compared to the Year Ended December 31, 2019

The information on pages 63-68 in our Annual Report 2020 under the heading "Financial Review" is incorporated herein by reference.

Financial Results for the Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

Discussion of the financial results for the year ended December 31, 2019 as compared to the year ended December 31, 2018 can be found in "Item 5A. Operating Results—Results of Operations—Financial Results for the Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018" in the Company's annual report on Form 20-F filed with the SEC on March 30, 2020.

## Significant Accounting Policies

The information in Note 1.1 to our Audited Financial Statements included in our Annual Report 2020 is incorporated herein by reference.

### Implementation of New and Revised Standards and Interpretations

The information in Note 1.2 to our Audited Financial Statements included in our Annual Report 2020 is incorporated herein by reference.

#### Standards and Interpretations Not Yet in Effect

The information in Note 1.2 to our Audited Financial Statements included in our Annual Report 2020 is incorporated herein by reference.

#### B. Liquidity and Capital Resources

The information on pages 67-68 in our Annual Report 2020 under the heading "Cash Position and Cash Flow" is incorporated herein by reference.

The description of our lease obligations in Note 3.3 to our Audited Financial Statements included in our Annual Report 2020 is incorporated herein by reference.

The description of our short term contractual obligations related to a number of agreements primarily related to research and development activities in Note 5.4 to our Audited Financial Statements included in our Annual Report 2020 is incorporated herein by reference.

The description of our contingent commitments under our license and collaboration agreements that may become due for future payments in Note 5.4 to our Audited Financial Statements included in our Annual Report 2020 is incorporated herein by reference. The contingent commitments entail uncertainties in relation to the period in which payments are due because these obligations are dependent on milestone achievements, most of which are not expected to be incurred within the next five years.

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally allow us the option to cancel, reschedule and adjust our requirements based on our business needs prior to the delivery of goods or performance of services. It is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

## C. Research and Development, Patents and Licenses, etc.

See "Item 4.B—Business Overview" and "Item 5.A—Operating Results".

### D. Trend Information

See "Item 5.A—Operating Results—Key Components of Our Results and Related Trends".

### **E.** Critical Accounting Estimates

Not applicable.

### ITEM 6 DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

## A. Directors and Senior Management

The following table sets forth the name, age and position of each of our board of directors ("**Board**") members as of the date of this Annual Report. Our Board consists of six members elected by our shareholders at the general meeting ("**Shareholder Elected Members**" and each, a "**Shareholder Elected Members**"), and three members elected by our

employees ("Employee Elected Members" and each, an "Employee Elected Member"). Shareholder Elected Members are elected by our shareholders every year and Employee Elected Members are elected by our employees every third year. The terms of office of the Shareholder Elected Members expire in 2021 and the terms of office of the Employee Elected Members expire in 2022. All members of the Board, however elected, are eligible for re-election.

The business address of our directors is our registered office address at c/o Genmab A/S, Kalvebod Brygge 43, 1560 Copenhagen V, Denmark.

Name of Board Member	Age	Position(s)
Deirdre P. Connelly	60	Chair (independent, Shareholder Elected)
Pernille Erenbjerg	53	Deputy Chair (independent, Shareholder Elected)
Anders Gersel Pedersen	69	Board member (non-independent, Shareholder Elected)
Paolo Paoletti	70	Board member (independent, Shareholder Elected)
Rolf Hoffmann	61	Board member (independent, Shareholder Elected)
Jonathan Peacock	63	Board member (independent, Shareholder Elected)
Peter Storm Kristensen	46	Board member (non-independent, Employee Elected)
Mijke Zachariasse	47	Board member (non-independent, Employee Elected)
Rima Bawarshi Nassar	67	Board member (non-independent, Employee Elected)

The following is a brief summary of the business experience of our Board members:

**Deirdre P. Connelly** was elected to the Board in 2017 and currently acts as Chair of the Board and as the Chair of the Compensation Committee. She is a member of the Audit and Finance Committee and the Nominating and Corporate Governance Committee. Ms. Connelly was formerly the President of North America Pharmaceuticals for GlaxoSmithKline plc from 2009 to 2015 and currently serves on the board of directors of Macy's, Inc. and of the Lincoln National Corporation. Prior to her time at GlaxoSmithKline plc, she spent 26 years with Eli Lilly and Company from 1984 to 2009, which included tenures as President of U.S. Eli Lilly and Company and Vice President of Human Resources and President of Global Women's Health. She holds a bachelor's degree in Economics and Marketing from Lycoming University and is a graduate of Harvard University's Advanced Management Program.

**Pernille Erenbjerg** was elected to the Board in 2015 and currently acts as Deputy Chair of the Board and as the Chair of the Audit and Finance Committee and as a member of the Nominating and Corporate Governance Committee. Ms. Erenbjerg qualified as a Certified Public Accountant, ("**CPA**") in 1994, but is no longer practicing as such. Ms. Erenbjerg qualifies as an audit committee financial expert. Ms. Erenbjerg previously served as the Group CEO and President of TDC A/S, and prior to that she served as the Group CFO of the same Company. She is a non-executive board member, Audit Committee member and member of the Operations and Sustainability Committee of Nordea AB. She is a non-executive board member, Deputy Chair, Chair of the Remuneration Committee and member of the Audit Committee of Millicom SA. She is a non-executive board member and member of the Audit Committee of Nordic Entertainment Group AB. She was formerly a non-executive member of the board, Deputy Chair of the Board and chair of the audit committee of DFDS A/S from 2014 to 2018 and a non-executive board member of the Royal Danish Theatre from 2011 to 2015. She is formerly a partner at Deloitte Touche Tohmatsu Limited and spent 14 years as a CPA at Arthur Anderson LLP from 1987 to 2002. Ms. Erenbjerg holds a B.S. and a M.Sc. in Economics from Copenhagen Business School.

Anders Gersel Pedersen was elected to the Board in 2003 and currently serves as the Chair of the Nominating and Corporate Governance Committee and is a member of the Scientific Committee and the Compensation Committee. Dr. Pedersen currently serves as the Chairman of the board of Aelis Farma, Deputy Chairman of the board of Bavarian Nordic A/S and as a member of the board of Hansa Medical AB and of Bond 2 development 2GP limited, and was formerly the Executive Vice President of Research & Development at H. Lundbeck A/S. Dr. Pedersen holds a medical degree and a doctoral degree in neuro-oncology from University of Copenhagen and a B.S. in Business Administration from Copenhagen Business School. He is a member of the European Society of Medical Oncology, the American Society of Clinical Oncology, the Danish Society of Medical Oncology, the Danish Society of Lung Cancer.

**Paolo Paoletti** was elected to the Board in 2015 and currently serves as the Chair of the Scientific Committee and is a member of the Compensation Committee. Dr. Paoletti served as President of Oncology at GlaxoSmithKline plc and in various roles at Eli Lilly and Company, including Vice President of Oncology Research. Dr. Paoletti is the CEO of GammaDelta Therapeutics Limited and is a member of the board of PsiOxus Therapeutics Limited and a member of the board of FORMA Therapeutics, Inc. He was formerly the CEO of Kesios Therapeutics Ltd. from 2015 to 2017 and previously served as a member of the board of NuCana BioMed Ltd. Dr. Paoletti holds a medical degree from the University of Pisa.

**Rolf Hoffmann** was elected to the Board in 2017 and is a member of the Audit and Finance Committee and the Scientific Committee. Mr. Hoffmann has over 20 years of experience in the international pharmaceutical and biotechnology industries at Eli Lilly and Company from 1987 to 2004 and Amgen Inc. from 2004 to 2016. Mr. Hoffmann is currently an adjunct professor of Strategy and Entrepreneurship at the University of North Carolina Business School and serves as Chairman of the board of directors at Biotest AG and as a board member at EUSA Pharma, Inc., Paratek Pharmaceuticals, Inc. and Shield Therapeutics plc. He holds an M.A. in English from the University of Cologne, an MA in Kinesiology from Deutsche Sporthochschule Köln in Cologne, Germany and an M.B.A. from the University of North Carolina at Chapel Hill.

**Jonathan Peacock** was elected to the Board in 2020 and is a member of the Audit and Finance Committee and the Compensation Committee. Mr. Peacock has extensive experience in corporate finance, strategy and international expansion in the pharmaceutical industry. He was involved in several large and small acquisitions and partnerships of commercial, pipeline and research assets covering diverse global markets as CFO at Novartis Pharma and CFO at Amgen. He serves as Chairman of the board of directors at Bellerophon Therapeutics Inc. and as a board member at Avantor Inc., W20 Group and a Trustee of the Natural History Museum of Los Angeles. Mr. Peacock holds a degree in Economics, is a chartered accountant and has a background as a partner at McKinsey and Price Waterhouse.

**Peter Storm Kristensen** was elected to the Board in 2016. Mr. Kristensen currently serves as our Director, Legal Lead Corporate. Prior to joining Genmab, he was a lawyer at Copenhagen University Hospital and Patienterstatningen from 2005 to 2007. He holds a law degree from the University of Copenhagen.

**Mijke Zachariasse** was elected to the Board in 2019. Dr. Zachariasse joined us in 2017 and currently serves as our Director of Protein Production and Chemistry. Prior to joining us, from 2010 to 2017, she was a Research Policy Advisor/Head of the Research Support Office at Utrecht University. From 2008 to 2010, Dr. Zachariasse was Managing Director of the Leiden Institute of Physics. Dr. Zachariasse served as a Programme Officer at the Foundation for Fundamental Research on Matter from 2002 to 2008. She received her Doctorate in Physics from the Technical University of Eindhoven in 2002.

**Rima Bawarshi Nassar** was elected to the Board in 2020. Dr. Nassar joined Genmab in 2018 and currently serves as our Vice President, Head of Regulatory Affairs. Prior to joining us, from 2012 to 2017, she was the Associate Vice President, Global Regulatory Affairs at Sanofi. Dr. Nassar received her Ph.D. in Pharmaceutical Sciences from the University of Kentucky.

## Senior Management

The following table sets forth information with respect to each of the members of our senior management, including their respective ages and their positions as of the date of this Annual Report. The business address of these members of our senior management is our registered office address at c/o Genmab A/S, Kalvebod Brygge 43, 1560 Copenhagen V, Denmark. We note that only Jan G. J. van de Winkel, Anthony Pagano, Judith Klimovsky, Anthony Mancini and

Tahamtan Ahmadi are registered with the Danish Business Authority as members of executive management, or registered managers, within the meaning of the Danish Companies Act ("DCA").

Name of Member of Senior Management	Age	Position(s)
Jan G. J. van de Winkel	60	President and Chief Executive Officer
Anthony Pagano	43	Executive Vice President and Chief Financial Officer
Judith Klimovsky	64	Executive Vice President and Chief Development Officer
Anthony Mancini	50	Executive Vice President and Chief Operating Officer
Tahamtan Ahmadi	48	Executive Vice President and Chief Medical Officer, Head of
		Experimental Medicines
Birgitte Stephensen	60	Senior Vice President, Head of Global IPR & Legal
Christopher Cozic	43	Senior Vice President, Global Human Resources
Martine J. van Vugt	51	Senior Vice President, Corporate Strategy and Planning

The following is a brief summary of the business experience of our senior management.

**Jan G. J. van de Winkel** is our co-founder and served as President, Research & Development and Chief Scientific Officer of the Company until his appointment as President & Chief Executive Officer in 2010. Dr. van de Winkel served as Vice President and Scientific Director of Medarex Europe prior to founding Genmab. Dr. van de Winkel holds a professorship of immunotherapy at Utrecht University. He is Chairman of the board of directors of Hookipa Pharma Inc. and a member of the board of directors of LEO Pharma A/S and Omega Alpha SPAC. He holds an M.Sc. and a Ph.D. from the University of Nijmegen in the Netherlands.

**Anthony Pagano** joined Genmab in 2007. His positions increased in seniority during his tenure with us and he currently serves as our Executive Vice President and Chief Financial Officer. Prior to joining us, Mr. Pagano was Corporate Controller and Senior Director of Business Planning at NovaDel Pharma, Inc. from 2005 to 2007, a publicly-traded specialty pharmaceutical company. He previously worked as a Manager at KPMG LLP from 1999 to 2005. He is a Certified Public Accountant and received a B.S. in Accounting from The College of New Jersey, as well as an M.B.A. from the Stern School of Business at New York University.

**Judith Klimovsky** joined us in 2017 and currently serves as the Executive Vice President and Chief Development Officer. She worked previously as a drug developer and has more than 20 years of experience in research and development leadership roles at Bristol-Myers Squibb Company and Novartis Pharma AG. Dr. Klimovsky is also a medical doctor who has worked as a clinician in hospital environments. Prior to joining us, she held various positions at Novartis Pharma AG from 2009 to 2017, including Senior Vice President, Head of Clinical Development. Dr. Klimovsky is a member of the board of directors of Bellicum Pharmaceuticals. She holds a medical degree from the Universidad de Buenos Aires in Argentina.

**Anthony Mancini** joined Genmab in March 2020 as Executive Vice President and Chief Operating Officer. Prior to joining Genmab, Mr. Mancini served in a variety of strategic and operational leadership roles over a nearly 24-year career at BMS. Most recently, he led BMS' US Innovative Medicines Unit, a team of over 1100 people focused on Immunology & Cardiovascular diseases. He holds a Bachelor of Science in Biochemistry from the University of Ottawa, Canada, an MBA from Clemson University, South Carolina, USA, and participated in the General Management Program, CEDEP at INSEAD, Fontainebleau, France.

**Tahamtan Ahmadi** joined us in 2017 and became the Executive Vice President and Chief Medical Officer, Head of Experimental Medicines effective March 1, 2021. Prior to that, Dr. Ahmadi was Head of Experimental Medicine and Early Development Oncology at Janssen and a member of the Senior Leadership Team for Oncology from 2012 to 2017. During his time at Janssen, he led the global development of daratumumab including clinical R&D and medical affairs strategy across indications. Dr. Ahmadi was previously a faculty member of the Department of Hematology and Oncology at the University of Pennsylvania. He holds an M.D. from the University of Cologne and a Ph.D. from the University of Freiburg, both in Germany, and has experience in translational research, strategic product development, global regulatory submissions and clinical development.

**Birgitte Stephensen** joined us in 2002 and was appointed Senior Vice President in 2010. Ms. Stephensen has experience in both private practice and industry working with legal and intellectual property matters within the pharmaceutical and biotechnology fields. Prior to joining us, Ms. Stephensen worked in a patent law firm from 1988 to 1997, and was with the patent department of Novo Nordisk A/S from 1997 to 2002. Ms. Stephensen qualified as a European patent attorney in 1994. She earned an M.Sc. from the School of Pharmaceutical Sciences at the University of Copenhagen.

**Christopher Cozic** joined Genmab in 2017. Prior to joining Genmab, Mr. Cozic was Vice President of Human Resources at Ipsen from 2014 to 2017. Previously, he spent over eight years at Eisai, where he served as Director, Global Human Resources, after joining the company in 2006. He received his bachelor's degree in English and Communications from Quinnipiac University and also attained Professional in Human Resources, Senior Professional in Human Resources, and Global Professional in Human Resources certifications.

**Martine J. van Vugt** started her professional career with us in 2001 and was appointed Senior Vice President in January 2019. Previously, she was responsible for our Portfolio, Project and Alliance Management as well as Strategic Initiatives and continues to oversee these areas. She has been active in business development operations since 2011. From 1998 until joining us in 2001, she studied dendritic cell vaccination therapy as a post-doctoral fellow. Dr. van Vugt holds an M.Sc. from the University of Wageningen and a Ph.D. from Utrecht University.

#### **B.** Compensation

In 2020, the aggregate remuneration paid to the Board was DKK 11.7 million.

No member of the Board is entitled to any kind of remuneration upon retirement from his or her position as a member of the Board. We have not allocated funds for any pension benefits, severance schemes or similar measures, or undertaken any other obligations to do so on behalf of the Board, and we have no obligation to do so.

In 2020, the aggregate remuneration to our executive management was DKK 80.6 million, all of which was fully accrued at December 31, 2020. This amount includes base salary, defined contribution plans, other benefits, share-based compensation expenses and annual cash bonuses. See Note 5.1 to our Audited Financial Statements included in our Annual Report 2020 for details on compensation of our executive management. In addition, the aggregate remuneration to our senior management was DKK 101.8 million, all of which was fully accrued at December 31, 2020, and includes the remuneration of our executive management and our extended senior leadership team.

Genmab A/S' shareholders have adopted a remuneration policy for the Board of Directors and Executive Management of Genmab A/S (the "Remuneration Policy").

## Compensation of Members of Our Board of Directors and Certain Members of Senior Management

See Note 4.6 and Note 5.1 to our Audited Financial Statements included in our Annual Report 2020 for warrants and RSUs granted to members of our Board and certain members of our senior management, as well as compensation in connection with their membership to the Board and our registered managers in connection with their employment with us.

### **Certain Senior Management Agreements**

Remuneration given to our President and CEO, Jan G. J. van de Winkel, our Executive Vice President and CFO, Anthony Pagano, our Executive Vice President and CDO, Judith Klimovsky, our Executive Vice President and COO, Anthony Mancini and our Executive Vice President and Chief Medical Officer, Head of Experimental Medicines, Tahamtan Ahmadi, in accordance with their service agreements consists of a base salary, a cash bonus, RSUs and warrants. The cash bonus for Dr. van de Winkel is in accordance with the Remuneration Policy and as determined by the Compensation Committee and approved by the Board in a range of 0 to 100 percent of his annual base salary. The cash bonuses for Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi are conditional upon the recommendation of the CEO, in an amount between 0 and 60 percent of the individual's annual base salary, in accordance with the

Remuneration Policy and as determined by the Compensation Committee and approved by the Board. RSUs have been granted to Dr. van de Winkel, Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi under our RSU program for the 2020 performance year on February 26, 2021. The above-named individuals qualify for all of our benefit programs, including pension plans.

Dr. van de Winkel, Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi can terminate their employment with us by giving a six-month notice. We can terminate their employment with us by giving them a 12-month notice. In the event that we terminate the service agreements without cause, we will be obliged to pay the then existing salary (including all benefits set forth in their respective service agreements) to Dr. van de Winkel for two years, and to Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi for one year, after the end of the 12-month notice period.

In the event of a termination by us without cause in connection with a change in control (as defined in the individuals' service agreements), the notice period will be extended up to 24 months in the first year after the change of control. In addition, we will pay an additional two years of then current salary (including all benefits set forth in his service agreement) to Dr. van de Winkel, and an additional year of then current salary (including all benefits set forth in their respective service agreements) to Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi. Dr. van de Winkel will also receive an amount equal to two times the highest total bonus awarded to him, and Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi will each receive an amount equal to the highest total bonus awarded to them, in any year during the term of their respective employment, in each case payable in a lump sum payment on the individual's last working day.

Other than as set out above, Dr. van de Winkel, Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi are not entitled to any kind of remuneration upon termination of employment. We have not granted any loans, issued any guarantees or undertaken any other obligations to do so on behalf of any member of our senior management.

For further details on the terms and conditions of the warrants, see "—Warrant Program" below. For further details on the terms and conditions of the RSUs, see "—Restricted Stock Unit Program" below.

Other than as set out above, no exceptional or extraordinary agreements, including agreements regarding bonus schemes, other than ordinary incentive schemes and remuneration of the senior management implying financial obligations for us, have been concluded with members of our senior management.

### Warrant Program

We have established a warrant program ("Warrant Program"), as an incentive for our employees and members of senior management. Warrants are granted by the Board in accordance with authorizations given to it by our shareholders. Warrant grants are subject to the relevant terms of our articles of association and, if applicable, the Remuneration Policy or any incentive guidelines or remuneration principles adopted by the shareholders at the general meeting preceding the Remuneration Policy. Under the terms of the Warrant Program, (i) warrants are granted at an exercise price equal to the share price on the grant date, (ii) the exercise price cannot be fixed at a lower price than the market price at the grant date and (iii) in connection with exercise, the warrants are to be settled with the delivery of our shares. The Warrant Program contains anti-dilution provisions if changes occur in our share capital prior to the warrants being exercised.

In case of a change of control event as defined in the Warrant Program amended in August 2004, April 2012 and March 2017, the warrant holder will immediately be granted the right to exercise all of his or her warrants regardless of the fact that such warrants would otherwise only become fully vested at a later point in time. Warrant holders who are no longer employed by or affiliated with us will, however, only be entitled to exercise such percentages of warrants as would otherwise have vested under the terms of the Warrant Program.

Warrants granted under the terms of the Warrant Program amended in August 2004, April 2012 and March 2017 are generally subject to provisions reflecting the principles of the former section 4 and 5 of the Danish Stock Option Act (*Aktieoptionsloven*), which allows for the forfeiture of unexercised warrants if the grantee separates from the company or one of our subsidiaries under circumstances in which the warrant holder is considered a "bad-leaver," understood as, for example, being dismissed for cause or resigning without us having materially breached the employment contract.

Warrant holders may maintain all granted warrants if they separate from the company or one of our subsidiaries under circumstances where they are considered as "good-leavers," such as dismissal without cause, leaving us pursuant to an agreed severance agreement or retirement, warrant holder's resignation due to our material breach of contract or the warrant holder's death.

Warrants granted on terms as amended in August 2004 can be exercised starting from one year after the grant date and lapse on the tenth anniversary of the grant date. As a general rule, the warrant holder may only exercise 25% of the warrants granted per full year of employment or affiliation with us after the grant date. However, the warrant holder will be entitled to continue to be able to exercise all warrants on a regular schedule in instances where the employment relationship is terminated by us without cause.

Warrants granted on terms as amended in April 2012 will lapse at the seventh anniversary of the grant date. All other terms of these warrants are identical to those issued pursuant to the August 2004 amendment.

Warrants granted on terms as amended in March 2017 are subject to a cliff vesting period and become fully vested three years from the date of grant. All other terms of such warrants are identical to those issued pursuant to the April 2012 amendment.

In February 2021, the Warrant Program was amended (the "2021 Warrant Program"). Under the terms of the 2021 Warrant Program, in case (1) of a change of control event as defined in the 2021 Warrant Program, (2) of certain other transactions as described in the 2021 Warrant Program or (3) a warrant holder's employment terms are materially changed to his or her detriment during the 12-month period following a change in control event, the Board may decide, in its sole discretion, to accelerate the vesting of the warrants held by such warrant holder.

Under the 2021 Warrant Program, if a warrant holder separates from the Company under circumstances in which the warrant holder is considered a "bad-leaver," such as being dismissed for cause or during the employment probationary period, unvested warrants will be forfeited. Warrant holders may maintain a pro rata portion of unvested warrants if they separate from the Company under circumstances where they are considered "good-leavers," such as dismissal without cause or termination of employment due to the Company's material breach of the warrant holder's employment terms. All unvested warrants will be forfeited in the event of termination of employment due to the warrant holder's death.

See Note 4.6 to our Audited Financial Statements included in our Annual Report 2020 for our outstanding warrants and a summary of the holders of such warrants as of December 31, 2020.

### Restricted Stock Unit Program

We have established an RSU program as an incentive for all our employees, members of senior management and members of the Board.

RSUs are granted and performance vesting criteria, if any, decided by the Board in its sole discretion. RSUs granted to members of senior management and members of the Board are subject to the Remuneration Policy or any incentive guidelines or remuneration principles adopted by the shareholders at the general meeting preceding the Remuneration Policy. Under the terms of the RSU program, RSUs are subject to a cliff vesting period and become fully vested on the first banking day of the month following a period of three years from the date of grant.

Under the terms of the RSU program amended in 2016, if an employee, member of senior management, or member of the Board ceases his or her employment or Board membership prior to the vesting date, all RSUs that are granted but not yet vested will lapse automatically. However, if an employee, a member of senior management or a member of the Board ceases employment or Board membership due to retirement or age limitation in our articles of association, death, serious sickness or serious injury then all RSUs that are granted, but not yet vested will remain outstanding and will be settled in accordance with their terms. In addition, for an employee or a member of senior management, RSUs that are granted but not yet vested will remain outstanding and will be settled in accordance with their terms in instances where the employment relationship is terminated by us without cause. Within 30 days of the vesting date, the holder of an RSU

receives one share in the Company for each RSU. We may, at our sole discretion in extraordinary circumstances, choose to make a cash settlement instead of delivering shares.

The RSU program contains anti-dilution provisions if changes occur in our share capital prior to the vesting date and provisions to accelerate vesting of RSUs in the event of a change of control as defined in the RSU program.

We intend to purchase our own shares in order to cover our obligations in relation to the RSUs. Authorization to purchase our own shares up to a nominal value of DKK 500,000 (500,000 shares) was given by the shareholders at the annual general meeting in March 2016. Pursuant to this authorization and to cover our obligations under the RSU program, in 2018, we acquired 125,000 of our treasury shares, representing approximately 0.2% of share capital, for DKK 146.2 million, including directly attributable costs. The March 2016 authorization expired in March 2021. Additionally, in March 2019, our shareholders authorized us to repurchase up to an additional nominal value of DKK 500,000 (500,000 shares). A portion of the shares that may be repurchased under this authorization may be used to cover our obligations in relation to the RSUs. The weighted average fair value of RSUs granted in 2020 was DKK 1,927.83. We commenced repurchases of our shares between February 24, 2021 and March 17, 2021 pursuant to the March 2016 authorization and the repurchases of shares from March 18, 2021 and thereafter pursuant to the March 2019 authorization, and expect such repurchases to be completed by June 30, 2021.

In February 2021, the RSU program was amended (the "2021 RSU Program"). Under the terms of the 2021 RSU Program, in case (1) of a change of control event as defined in the 2021 RSU Program, (2) of certain other transactions as described in the 2021 RSU Program or (3) a participant's employment terms are materially changed to his or her detriment during the 12-month period following a change in control event, or if the participant, who is a member of the Board, is replaced by a new board member or such participant's seat on the Board is eliminated due to a reduction in the number of board members, the Board may decide, in its sole discretion, to accelerate the vesting of the RSUs held by such participant, or accelerate the vesting of the RSUs and make a cash settlement.

Under the terms of the 2021 RSU Program, in the event an RSU holder separates from the Company under circumstances in which the RSU holder is considered a "bad-leaver," such as being dismissed for cause or during the employment probationary period, unvested RSU will be forfeited. RSU holders may maintain a pro rata portion of unvested RSUs if they separate from the Company under circumstances where they are considered "good-leavers," such as dismissal without cause or termination of employment due to the Company's material breach of the RSU holder's employment terms, or if the participant is a member of the Board, if the membership of the Board ceases for any other reason than as a result of the participants death. All unvested RSUs will be forfeited in the event of termination of employment due to the RSU holder's death.

See Note 4.6 to our Audited Financial Statements included in our Annual Report 2020 for our outstanding RSUs and a summary of the holders of such RSUs as of December 31, 2020.

### **Insurance and Discharge of Liability**

According to the DCA, shareholders, at the general meeting, are permitted to discharge our Board members and registered managers from liability for any particular financial year based on a resolution relating to the period covered by the financial statements for the previous financial year. This discharge means that the shareholders will relieve such Board members and registered managers from liability to us. However, shareholders cannot discharge any claims by individual shareholders or other third parties. In addition, the discharge can be set aside in case the general meeting prior to its decision to discharge was not presented with all reasonable information necessary for the general meeting to assess the matter at hand.

In addition, we provide our Board members and registered managers with directors' and officers' liability insurance.

We have not granted any loans, guarantees, or other commitments to or on behalf of any members of our board of directors or senior management.

### **Employment Agreement and Warrant Grants**

We have entered into employment agreements with, and issued warrants to, our senior management. See "—Compensation—Certain Senior Management Agreements" and "—Compensation—Warrant Program" for more information.

#### C. Board Practices

#### **Board of Directors**

The Board plays an active role in setting our strategies and goals and monitoring our operations and results. Board duties include establishing policies for strategy, accounting, organization and finance and the appointment of the Company's registered managers. The Board also assesses our capital and share structure and is responsible for approving share issues and the grant of warrants and RSUs. In addition, the Board ensures that our affairs are managed in accordance with our articles of association and applicable law.

The Board performs its duties in accordance with the rules of procedure of the Board. The rules of procedure are reviewed and updated by all members of the Board on a regular basis. The Board meets for at least eight scheduled face-to-face, telephonic, videoconference or Teams meetings during the year. During 2020, the Board held eleven meetings in addition to the informal ongoing communication between Board members and our CEO. Our Board may consist of between three and nine Shareholder Elected Members, elected for terms of one year, with possibility of re-election. In addition, our employees may, pursuant to Danish statutory rules regarding the representation of employees on the board of directors and election regulations adopted by the Board, elect employee representatives to the Board, for terms of three years, with possibility of re-election. The employees of the Company have adopted a voluntary program which allows for election of employee representatives from the Company's directly and indirectly owned subsidiaries. Currently, the Board has three Employee Elected Members, Peter Storm Kristensen, Mijke Zachariasse and Rima Bawarshi Nassar. In total, our Board currently consists of nine Board members (including six Shareholder Elected Members and three Employee Elected Members). The Board elects a chair and deputy chair from among its members. The majority of our Board members are considered to be independent under the corporate governance standards of the Nasdaq Stock Market and Nasdaq Copenhagen.

#### Senior Management

Registered managers are appointed by the Board, which sets out the terms and conditions of their employment and the framework for their duties. Registered managers are responsible for our day to day management, including all assignments that rest upon them according to the Board and under Danish law, in compliance with the guidelines and directions issued by the Board. Management of our day to day operations does not include transactions of an unusual nature or of significant importance, or transactions being outside our business plan, which must be authorized by the Board. Registered managers appoint other members of senior management.

# Committees of the Board of Directors

The Board has established and appointed a Compensation Committee, an Audit and Finance Committee, a Nominating and Corporate Governance Committee and a Scientific Committee. These committees are charged with reviewing issues pertaining to their respective fields that are due to be considered at Board meetings. Under Danish corporate law, it is not possible to delegate the decision-making authority of the entire Board to board committees. Written charters specifying the tasks and responsibilities for each of the committees have been adopted by the Board.

# Audit and Finance Committee

According to the Audit and Finance Committee charter, the Audit and Finance Committee must consist of at least three non-executive Board members, all of whom must be independent. Furthermore, the Chair of the Board shall not be Chair of the Audit and Finance Committee. As of the date of this Annual Report, the Audit and Finance Committee consists of members Jonathan Peacock, Rolf Hoffmann and Deirdre P. Connelly and is chaired by Pernille Erenbjerg.

The Audit and Finance Committee assists the Board with the oversight of the financial reporting process, the effectiveness of internal controls over financial reporting and risk management, the independent audit process and compliance with legal and regulatory requirements, in accordance with the Audit and Finance Committee charter. Each member of the Audit and Finance Committee satisfies the independence requirements of the corporate governance standards of the Nasdaq Stock Market, and Pernille Erenbjerg qualifies as an "Audit Committee financial expert," as defined in Nasdaq Rule 5605(c)(2) (A) and as determined by our Board.

Our Audit and Finance Committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. Our Audit and Finance Committee has the following principal responsibilities:

- overseeing the accounting and financial reporting principles and process to ensure compliance with legal and regulatory requirements and the quality, transparency and integrity of the published financial information;
- overseeing the appropriateness and effectiveness of our internal controls over financial reporting and risk management system and evaluating the need for an internal audit;
- overseeing our audits and the independent auditor process, including recommending the appointment of the
  independent auditors and overseeing the annual assessment of their performance and qualifications,
  overseeing non-audit services and, to the extent permitted by applicable law, being directly responsible for
  the appointment, retention and compensation of the independent auditors in connection with audit, review or
  attestation services;
- considering the independence of the independent auditors and any potential conflicts of interest, including by (i) ensuring receipt from the independent auditors of a formal written statement delineating all relationships with the Company, (ii) actively engaging in dialogue with the independent auditors with respect to factors that may impact the independent auditors' objectivity and independence, and (iii) taking, or recommending that the Board takes, appropriate action to oversee auditor independence;
- ensuring that significant adjustments, unadjusted differences, disagreements between management and the
  independent auditors and management responses thereto are discussed with the independent auditors and
  resolving disagreements between management and the independent auditors;
- assessing transactions between the Company and the Company's related parties and, in respect of material
  related party transactions, submitting a recommendation for approval or non-approval of such transactions to
  the Board prior to their completion;
- overseeing compliance with legal and regulatory requirements in relation to financial reporting and auditing regulation;
- authority to obtain advice and assistance from independent counsel and other advisors;
- obtaining appropriate funding, as determined by the Audit and Finance Committee, for compensation to the independent auditor and to any advisors that the Audit and Finance Committee chooses to engage;
- undertaking the whistleblower function, including establishment of procedures for the receipt, retention and treatment of any complaints, including confidential anonymous submissions from our employees regarding accounting, auditing and internal control issues received through a formalized complaint process, as well as review of such complaints; and
- evaluating its own performance and the achievement of its duties on a regular basis, and annually reviewing
  and updating the Audit and Finance Committee charter and discussing any required changes thereto with the
  Board.

The Audit and Finance Committee also performs such other functions and exercises such other powers as may be delegated to it by the Board from time to time.

### Compensation Committee

According to its charter, our Compensation Committee must consist of at least two non-executive directors, appointed by the Board. A majority of the members must be independent. As of the date of this Annual Report, the Compensation Committee consists of members Jonathan Peacock, Paolo Paoletti and Anders Gersel Pedersen and is chaired by Deirdre P. Connelly. Jonathan Peacock, Paolo Paoletti and Deirdre P. Connelly satisfy the independence requirements of the corporate governance standards of the Nasdaq Stock Market. In accordance with the Danish corporate governance recommendations, we consider Anders Gersel Pedersen non-independent solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. The Compensation Committee assists the Board in the areas of compensation of managers and the adoption of policies that concern our compensation programs, including equity-based programs and benefit plans. The Compensation Committee also makes recommendations to the Board regarding specific remuneration packages for each of the members of the Board as well as our registered managers, including pension rights and any compensation payments. The proposed remuneration policy, if adopted by the Board, are subject to the approval of our shareholders at the annual general meeting. The Compensation Committee's primary responsibilities are as follows:

- reviewing trends in compensation and the competitiveness of our executive compensation programs to ensure

   (a) the attraction and retention of registered managers,
   (b) the motivation of registered managers to achieve our business objectives,
   (c) the alignment of the interests of key leadership with the long-term interests of our shareholders;
- making proposals for the approval of the Board prior to approval by shareholders at the general meeting, on
  the remuneration policy for members of the Board and the registered managers, including the overall
  principles of incentive pay schemes, compensation structure and long-term incentive compensation plans and
  a remuneration policy applicable to the Company in general;
- reviewing goals and objectives of our CEO and evaluating his performance to make recommendations concerning CEO compensation upon deliberations or voting in the CEO's absence;
- overseeing the evaluation of the performance of the Company's registered managers, and discussing their annual compensation, including salary, bonus, incentive and equity compensation;
- reviewing plans for registered managers' development and corporate succession plans for registered management;
- reviewing termination and compensation packages for new registered managers as requested by management;
- in its sole discretion, retaining, terminating and receiving advice from outside counsel, compensation consultants or other advisers, upon consideration of (i) whether such counsel, consultant or adviser provides other services to the Company and the amount of fees they receive from the Company as a percentage of their total revenue, (ii) the policies of such counsel, consultant or adviser designed to prevent conflicts of interest, (iii) any business or personal relationship of the consultant, counsel or adviser with a member of the Compensation Committee or a member of senior management of the Company, and (iv) any ownership of shares in the Company by the consultant, legal counsel or adviser;
- approving the fees of outside counsel, compensation consultants or other advisers, to be appropriately funded by the Company and directly overseeing the work of such counsel, consultants or advisers; and

 overseeing that the information in the annual report on the compensation of the Board and registered managers is correct, true and sufficient.

The Compensation Committee also performs such other functions and exercises such other powers as may be delegated to it by the Board from time to time.

Nominating and Corporate Governance Committee

According to its charter, our Nominating and Corporate Governance Committee must include at least two non-executive directors, appointed by the Board. A majority of members must be independent. As of the date of this Annual Report, the Nominating and Corporate Governance Committee consists of members Pernille Erenbjerg and Deirdre P. Connelly and is chaired by Anders Gersel Pedersen. Pernille Erenbjerg and Deirdre P. Connelly satisfy the independence requirements of the corporate governance standards of the Nasdaq Global Select Market. In accordance with the Danish corporate governance recommendations, we consider Anders Gersel Pedersen non-independent solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. The Nominating and Corporate Governance Committee identifies, reviews, evaluates and recommends to the full Board candidates to serve as directors of the Company and makes recommendations to the Board regarding Board and committee members and corporate governance issues. The Nominating and Corporate Governance Committee's primary responsibilities include the following:

- proposing to the full Board policies on the size and composition of the Board, including proposals for specific changes to Board size, composition or internal rules of the Board;
- describing the qualifications required for the Board and the registered managers and for a given position and identifying and recommending qualified candidates to the Board;
- evaluating at least annually the skills, knowledge and experience of the individual members of the Board and
  the registered managers and evaluating, reviewing and considering whether to recommend existing directors
  for re-election;
- maintaining an orientation and continuing education program for directors;
- establishing a process for the periodic review and assessment of the performance of the Board and its
  committees and conducting such review of the structure and performance of each board committee and
  committee member, recommending any changes considered appropriate, as well as recommending the
  establishment of new or special committees as desirable or necessary from time to time;
- periodically assessing the independence of directors and our corporate governance principles and their
  application, and recommending any changes deemed appropriate to the Board, including in connection with
  any proposals submitted by shareholders that relate to corporate governance, corporate social responsibility
  and environment, social and governance matters;
- overseeing and reviewing the processes and procedures in place to ensure that the Board and its committees timely receive accurate, relevant and appropriately detailed information;
- reviewing the adequacy of internal rules of the Board, management and any other codes of ethics with the Board and management;
- overseeing our policies and practices regarding philanthropic and political activities; and
- periodically reviewing, discussing and assessing the performance of the committee as well as the adequacy of its charter, and recommending any proposed changes to the Board for approval.

# Scientific Committee

According to its charter, the Scientific Committee must include at least three non-executive directors, the majority of whom must be independent, with a broad scientific and medical understanding and experience, appointed by the Board. As of the date of this Annual Report, the Scientific Committee consists of members Anders Gersel Pedersen and Rolf Hoffmann and is chaired by Paolo Paoletti. The Scientific Committee provides input and advises the Board in matters relating to our research and development strategy, including reviewing our pre-clinical and clinical product pipeline in view of our overall strategy and vision. The Scientific Committee's primary responsibilities include the following:

- reviewing and discussing our pre-clinical and clinical product portfolio, including the commercial attractiveness and the ranking thereof;
- reviewing and discussing our research and development strategy and reviewing scientific and technological trends that we believe are of significant importance and providing strategic advice and making recommendations with respect to our ongoing research and development programs;
- reviewing the quality of our research and development capacity and its organization, including the product development process; and
- reviewing and discussing the Company's intellectual property strategies.

### D. Employees

As of December 31, 2020, we had 781 employees. Of these employees, 647 were engaged in or support research and development and 134 were in administrative and business related positions. Each of our employees has signed confidentiality and inventions assignment agreements, or have signed employment agreements containing confidentiality and inventions assignment provisions, and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

# E. Share Ownership

For information regarding the share ownership of our directors and members of senior management, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

# ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

# A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our shares as of March 29, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own equal to or more than 5% of our outstanding shares;
- each of our directors; and
- · each member of our senior management

	Share Beneficial Ownership Number of			
Name of Beneficial Owner	Number of Shares Beneficially Owned	Warrants Exercisable and RSUs to be Settled Within 60 days	Fully Diluted Number of Shares Beneficially Owned	Fully Diluted Percentage of Beneficial Ownership
5% Shareholders				
Artisan Partners Limited Partnership <sup>(1)</sup>			4,256,006	6.49 %
BlackRock, Inc. <sup>(2)</sup>			4,789,616	7.30 %
<b>Board Members and Senior Management</b>				
Deirdre P. Connelly	3,859	_	3,859	0.01 %
Pernille Lyngvold Erenbjerg	3,959	_	3,959	0.01 %
Anders Gersel Pedersen	12,388	_	12,388	0.02 %
Paolo Augusto Paoletti	1,418	_	1,418	0.00 %
Rolf Hoffmann	2,559	_	2,559	0.00 %
Jonathan Peacock	763	_	763	0.00 %
Mijke Zachariasse	34	240	274	0.00 %
Peter Storm Kristensen	883	1,452	2,335	0.00 %
Rima Nassar	_	3,262	3,262	0.00 %
Jan van de Winkel	645,460	42,402	687,862	1.05 %
Anthony Pagano	1,929	19,145	21,074	0.03 %
Anthony Mancini	_	_	_	0.00 %
Judith Klimovsky	3,544	21,879	25,423	0.04 %
Tahamtan Ahmadi	1,257	11,476	12,733	0.02 %
Birgitte Stephensen	*	*	*	*
Christopher Cozic	*	*	*	*
Martine van Vugt	*	*	*	*
All board members and senior management as a				
group (17 persons)	683,257	121,500	804,757	1.23 %

<sup>\*</sup> Indicates beneficial ownership of less than 1% of the total outstanding shares.

The number of shares beneficially owned by each entity, person or member of our board of directors or senior management is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares for which the individual has the right to subscribe within 60 days of March 29, 2021 through the exercise of any options, warrants or other rights. There are 121,500 shares for which our board members and senior management as a group have the right to subscribe within 60 days of March 29, 2021 pursuant to the exercise of warrants or settlement of restricted stock units.

Subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares owned by that person. The percentage of shares beneficially owned is computed on the basis of 65,587,322 shares outstanding as of March 29, 2021. Shares for which a person has the right to subscribe within 60 days of March 29, 2021 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person. We conducted our last beneficial ownership analysis in the second quarter of 2020 and we estimated that approximately 38%, or 25 million (including shares in the form of ADSs) of our outstanding shares as of such date, were beneficially held by U.S. residents.

<sup>(1)</sup> This information is based solely on the Form 13F filed by Artisan Partners Limited Partnership on November 12, 2020. Artisan Partners Limited Partnership does not have different voting rights from other shareholders.

<sup>(2)</sup> This information is based solely on the Schedule 13G filed by BlackRock, Inc. on January 29, 2021 with the SEC. BlackRock, Inc. does not have different voting rights from other shareholders.

# **B.** Related-Party Transactions

In the year ended December 31, 2020, there were no material related party transactions. The Company has employment agreements with, and has made equity compensation grants to, members of senior management in the ordinary course of business.

# C. Interests of Experts and Counsel

Not applicable.

### ITEM 8 FINANCIAL INFORMATION

# A. Consolidated Statements and Other Financial Information

#### **Financial Statements**

See "Item 18—Financial Statements" which contains our financial statements prepared in accordance with IFRS.

# **Legal Proceedings**

From time to time in the ordinary course of business we may become involved in various lawsuits, claims and proceedings relating to the conduct of our business, including those pertaining to the defense and enforcement of our patent or other intellectual property rights. These proceedings are costly and time consuming. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary products and technologies without a license from us or our partners.

For example, in September 2020, Genmab commenced binding arbitration of two matters arising under its license agreement with Janssen Biotech, Inc. (Janssen) relating to daratumumab. Under the license agreement, Genmab is, among other things, entitled to royalties from Janssen on sales of daratumumab (marketed as DARZALEX for intravenous administration and for SubQ administration marketed as DARZALEX *FASPRO* in the United States and DARZALEX SC in Europe ). The arbitration first is to settle whether Genmab is required to share in Janssen's royalty payments to Halozyme for the Halozyme enzyme technology used in the SubQ formulation of daratumumab. The royalties Janssen pays to Halozyme represent a mid-single digit percentage rate of SubQ daratumumab sales. Janssen has started reducing its royalty payments to Genmab by what it claims to be Genmab's share of Janssen's royalty payments to Halozyme beginning in the second quarter of 2020 and has continued to do so through December 31, 2020. The arbitration is also to settle whether Janssen's obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-to-expire relevant Janssen-owned patent covering the product, as further defined and described in the license agreement.

# **Dividends**

We do not currently pay out cash dividends on our shares and have not paid out any dividends within the last three financial years. Any future determination related to our dividend policy and the declaration of any dividends will be made at the discretion of our Board of Directors and will depend on a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

# **B.** Significant Changes

# Tahamtan Ahmadi Appointed to Newly Created Position of Chief Medical Officer, Head of Experimental Medicine

Effective March 1, 2021 Tahamtan Ahmadi was appointed Executive Vice President and Chief Medical Officer, Head of Experimental Medicine. Dr. Ahmadi will lead Genmab's research, discovery, regulatory and medical activities.

# ITEM 9 THE OFFER AND LISTING

# A. Offer and Listing Details

Our shares are listed on NASDAQ Copenhagen in Denmark under the symbol "GMAB." Our ADSs are listed on the NASDAQ in the United States under the symbol "GMAB."

### B. Plan of Distribution

Not applicable.

## C. Markets

Our shares have been publicly traded since October 2000 and have been listed on NASDAQ Copenhagen in Denmark since that time.

ADSs representing the shares, as evidenced by ADSs issued by Deutsche Bank Trust Company Americas, as the Depository, have been listed on the NASDAQ since July 2019.

# D. Selling Shareholders

Not applicable.

### E. Dilution

Not applicable.

# F. Expenses of the Issue

Not applicable.

# ITEM 10 ADDITIONAL INFORMATION

# A. Share Capital

Not applicable.

# B. Memorandum and Articles of Association

The sections entitled "Description of Share Capital and Certain Corporate Matters—Shareholders' Register," "Description of Share Capital and Certain Corporate Matters—Articles of Association and Danish Corporate Law" and "Description of Share Capital and Certain Corporate Matters—Comparison of Danish Corporate Law and our Articles of Association and Delaware Corporate Law" in the Company's prospectus, filed with the SEC on July 19, 2019 are incorporated herein by reference.

# C. Material Contracts

Except as otherwise disclosed in this Annual Report (including the Exhibits), we are not currently party to any material contract, other than contracts entered into in the ordinary course of business.

# **D.** Exchange Controls

There are no governmental laws, decrees, or regulations in Denmark (including, but not limited to, foreign exchange controls) that restrict the export or import of capital, or that affect the remittance of dividends, interest or other payments to non-resident holders of the shares or the ADSs (please see below under "Item 10.E—Taxation" in respect of Danish withholding tax on dividends). There are no limitations on the right of non-resident or foreign owners to hold or vote the shares or the ADSs imposed by the laws of Denmark or the Articles of Association of the Company solely due to the fact that such holders are non-residents or foreign owners.

### E. Taxation

# **Payment of Taxes**

Holders will be responsible for any taxes or other governmental charges payable, or which become payable, on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register or transfer their ADSs or allow holders to withdraw the deposited securities represented by their ADSs until such taxes or other charges are paid. It may apply payments owed to holders or sell deposited securities represented by their ADSs to pay any taxes owed and holders will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to holders any net proceeds, or send to holders any property, remaining after it has paid the taxes. Holders agree to indemnify us, the depositary, the custodian and each of our and their respective agents, directors, employees and affiliates for, and hold each of them harmless from, any claims with respect to taxes (including applicable interest and penalties thereon) arising from any refund of taxes, reduced rate of withholding at source or other tax benefit obtained for holders. Holders' obligations under this paragraph shall survive any transfer of ADRs, any surrender of ADRs and withdrawal of deposited securities or the termination of the deposit agreement.

#### Material U.S. Federal Income Tax Considerations

### General

The following discussion is a summary of the material U.S. federal income tax consequences relating to the acquisition, ownership and disposition of the ADSs. This summary does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a particular person's decision to acquire the ADSs. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, and U.S. Treasury regulations promulgated thereunder ("**Treasury Regulations**"), as well as judicial and administrative interpretations thereof as in effect as of the date of this Annual Report. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below, and there can be no assurance that the U.S. Internal Revenue Service ("**IRS**"), or U.S. courts will agree with the tax consequences described in this summary. The Company undertakes no obligation to publicly update or otherwise revise this summary whether as a result of new Treasury Regulations, Code sections, judicial and administrative interpretations or otherwise.

This summary applies only to U.S. Holders (as defined below) that hold the ADSs as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). This summary does not address any U.S. federal estate and gift tax, alternative minimum tax or Medicare tax on net investment income consequences, or any U.S. state or local or non-U.S. tax consequences. This summary also does not address the tax considerations that may be relevant to certain types of investors subject to special treatment under U.S. federal income tax laws, such as:

- banks and other financial institutions;
- insurance companies;
- regulated investment companies or real estate investment trusts;
- dealers or traders in securities or currencies that use a mark-to-market method of accounting;
- broker-dealers;
- tax exempt organizations, retirement plans, individual retirement accounts and other tax deferred
- persons holding the ADSs as part of a straddle, hedging, conversion or integrated transaction for U.S. federal income tax purposes;
- U.S. expatriates;
- U.S. Holders whose functional currency is not the U.S. dollar;
- any entity or arrangement classified as a partnership for U.S. federal income tax purposes or investors therein:
- persons who own or are deemed to own, directly or constructively, 10% or more of the total combined voting power of all classes of the Company's voting stock or 10% or more of the total value of shares of all classes of the Company's stock;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the ADSs being taken into account in an applicable financial statement;
- persons who acquire ADSs pursuant to the exercise of an employee stock option or otherwise as compensation; or
- persons holding the ADSs in connection with a trade or business conducted outside the United States

THE SUMMARY OF U.S. FEDERAL INCOME TAX CONSEQUENCES SET OUT BELOW IS FOR GENERAL INFORMATION ONLY. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ADSS.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of the ADSs that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or other entity treated as a corporation) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a court within the United States and the control of
  one or more U.S. persons for all substantial decisions of the trust or (2) has a valid election in effect
  under applicable Treasury Regulations to be treated as a U.S. person.

The U.S. federal income tax treatment of a partner in an entity or arrangement treated as a partnership for U.S. federal income tax purposes that holds ADSs generally will depend on the status of the partner and the activities of the partnership. Partnerships considering an investment in the ADSs and partners in such partnerships should consult their tax advisors regarding the specific U.S. federal income tax consequences to them of the acquisition, ownership and disposition of the ADSs.

The discussion below assumes that the representations contained in the deposit agreement and any related agreement are true and that the obligations in such agreements will be complied with in accordance with their terms.

#### **ADSs**

For U.S. federal income tax purposes, U.S. Holders of ADSs generally will be treated as the beneficial owners of the underlying shares represented by the ADSs and an exchange of ADSs for the underlying shares generally will not be subject to U.S. federal income tax.

The U.S. Treasury Department and the IRS have expressed concerns that U.S. Holders of ADSs may be claiming foreign tax credits in situations where an intermediary in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS has taken actions that are inconsistent with the U.S. Holder of the ADS being treated as the beneficial owner of the underlying security. Such actions (for example, a pre-release of an ADS by a depositary) also may be inconsistent with the claiming of the reduced rate of tax applicable to certain dividends received by non-corporate U.S. Holders of ADSs, including individual U.S. Holders. Accordingly, the availability of foreign tax credits or the reduced U.S. federal income tax rate for "qualified dividend income," each discussed below, could be affected by actions taken by intermediaries in the chain of ownership between the holder of an ADS and the Company, if as a result of such actions the U.S. Holder of an ADS is not properly treated as the beneficial owner of the underlying share.

# **Dividends and Other Distributions**

Subject to the PFIC rules discussed below, the gross amount of any distribution made by the Company to a U.S. Holder with respect to the ADSs (including the amount of any taxes withheld therefrom) generally will be included in such holder's gross income as non-U.S. source dividend income in the year actually or constructively received by the depository, but only to the extent that the distribution is paid out of the Company's current or accumulated earnings and profits (as determined under U.S. federal income tax principles). As a non-U.S. company, the Company does not maintain calculations of its earnings and profits under U.S. federal income tax principles. Therefore, it is expected that any distributions generally will be reported to U.S. Holders as dividends. Any dividends that the Company pays will not be eligible for the dividends-received deduction allowed to qualifying corporations under Section 243 of the Code.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends paid on the ADSs may be eligible to be taxed at favorable rates applicable to "qualified dividend income," provided that (1) the ADSs are readily tradable on an established securities market in the United States, (2) the Company is not a PFIC (as discussed

below) with respect to the relevant U.S. Holder for either its taxable year in which the dividend is paid or the preceding taxable year and (3) certain minimum holding period and other requirements are met.

Under a published IRS Notice, common or ordinary shares, or ADSs representing such shares, are considered to be readily tradable on an established securities market in the United States if they are listed on the Nasdaq Global Select Market, as our ADSs are expected to be. However, based on existing guidance, it is unclear whether the shares will be considered to be readily tradable on an established securities market in the United States, because only the ADSs, and not the underlying shares, will be listed on a securities market in the United States. U.S. Holders should consult their tax advisors regarding the availability of the favorable rate applicable to qualified dividend income for any dividends the Company pays with respect to the ADSs.

The amount of any distribution paid in Danish kroner will be included in a U.S. Holder's income in an amount equal to the U.S. dollar value of such Danish kroner calculated by reference to the exchange rate in effect on the date the distribution is actually or constructively received by the depository, regardless of whether the payment is in fact converted into U.S. dollars at that time. If the distribution is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the distribution. A U.S. Holder may have foreign currency gain or loss if the distribution is converted into, or exchanged for, U.S. dollars after the date of receipt.

Any dividends the Company pays to U.S. Holders generally will constitute non-U.S. source "passive category" income for U.S. foreign tax credit limitation purposes. If any Danish taxes are withheld with respect to dividends paid to a U.S. Holder with respect to the ADSs, subject to certain conditions and limitations provided in the Code and the applicable Treasury Regulations (including a minimum holding period requirement), such taxes may be treated as non-U.S. taxes eligible for credit against such U.S. Holder's U.S. federal income tax liability (to the extent not exceeding the withholding rate applicable to the U.S. Holder). In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct non-U.S. taxes, including any Danish taxes withheld from dividends on the ADSs, in computing their taxable income, subject to generally applicable limitations under U.S. federal income tax law. An election to deduct non-U.S. taxes instead of claiming foreign tax credits applies to all non-U.S. taxes paid or accrued in the taxable year. If a refund of the tax withheld is available under the laws of Denmark or under an applicable income tax treaty, the amount of tax withheld that is refundable will not be eligible for such credit against a U.S. Holder's U.S. federal income tax liability (and will not be eligible for the deduction against U.S. federal taxable income). If the dividends constitute qualified dividend income as discussed above, the amount of the dividend taken into account for purposes of calculating the U.S. foreign tax credit limitation generally will be limited to the gross amount of the dividend, multiplied by the reduced rate applicable to the qualified dividend income, divided by the highest rate of tax normally applicable to dividends.

The rules relating to the determination of the U.S. foreign tax credit and the deduction of non-U.S. taxes are complex, and U.S. Holders should consult their tax advisors to determine whether and to what extent a credit or deduction may be available in their particular circumstances.

# Taxable Dispositions of the ADSs

Subject to the PFIC rules discussed below, a U.S. Holder generally will recognize taxable gain or loss on any sale, exchange or other taxable disposition of an ADS in an amount equal to the difference between the sum of the fair market value of any property and the amount of cash received in such disposition and the holder's tax basis in the ADS. The U.S. Holder's tax basis in the ADSs generally will equal the cost of the ADSs to the U.S. Holder. The gain or loss generally will be capital gain or loss, and generally will be a long term capital gain or loss if the U.S. Holder has held the ADS for more than one year at the time of disposition. For certain non-corporate taxpayers (including individuals), long term capital gains are subject to tax at favorable rates. The deductibility of capital losses is subject to limitations.

Any gain or loss that a U.S. Holder recognizes on a sale or other taxable disposition of an ADS generally will be treated as U.S. source income or loss for U.S. foreign tax credit limitation purposes. U.S. Holders should consult their

tax advisors regarding the proper treatment of any gain or loss in their particular circumstances, including the effects of any applicable income tax treaties.

# Passive Foreign Investment Company Considerations

Based on the current and anticipated value of our assets and the nature and composition of the Company's income and assets, the Company does not expect to be a PFIC for our current taxable year ending December 31, 2021, or in the foreseeable future. However, the determination of PFIC status is based on an annual determination that cannot be made until the close of a taxable year, involves extensive factual investigation, including ascertaining the fair market value of all of our assets on a quarterly basis and the active or passive character of each item of income that we earn, and is subject to uncertainty in several respects. Changes in the nature or composition of our income or assets, the structure of our operation or the value of our assets may cause us to become a PFIC. The determination of the value of our assets may depend in part upon the value of our goodwill not reflected on our balance sheet (which may depend upon the market value of the ADSs from time to time, which may be volatile). Accordingly, we cannot assure you that we will not be a PFIC for our current taxable year ending December 31, 2021, or for any future taxable year. If we are a PFIC for any year during which a U.S. Holder holds the ADSs, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds the ADSs, even if we ceased to meet the threshold requirements for PFIC status in any particular year, unless the U.S. Holder has made a "deemed sale" election under the PFIC Rules when we cease to be a PFIC.

A non-U.S. corporation such as the Company will be treated as a PFIC for U.S. federal income tax purposes for any taxable year if, applying applicable look-through rules, either:

- at least 75% of its gross income for such year is "passive income" for purposes of the PFIC rules; or
- at least 50% of the value of its assets (generally, determined based on a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income.

For this purpose, passive income generally includes dividends, interest, royalties and rents other than certain royalties and rents derived in the active conduct of a trade or business and not derived from a related person. The Company will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, more than 25% by value of the stock.

For purposes of the income test, we believe that we are engaged in an active trade or business of discovering and developing antibody therapeutics and that the royalties and milestone payments we receive from unrelated parties should be treated as derived in the active conduct of a trade or business and not characterized as passive income. However, we have no assurance that these anticipated milestone payments and royalties will be paid when expected. If any such payments are delayed or not received then, depending on the amount of passive income we receive from other sources, the relative percentage of our income that is passive could increase and potentially cause us to be classified as a PFIC. There can be no assurances that we will not be classified as a PFIC for the current taxable year or for any future taxable year.

If we were a PFIC for any taxable year during which a U.S. Holder holds ADSs, then, unless such U.S. Holder makes a "mark-to-market" election (as discussed below), such U.S. Holder generally would be subject to special adverse tax rules with respect to any "excess distribution" that it receives from the Company and any gain that it recognizes from a sale or other disposition, including, in certain circumstances, a pledge, of ADSs. For this purpose, distributions that a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions that it received during the shorter of the three preceding taxable years or its holding period for the ADSs will be treated as an excess distribution. Under these rules:

 the excess distribution or recognized gain would be allocated ratably over the U.S. Holder's holding period for the ADSs;

- the amount of the excess distribution or recognized gain allocated to the taxable year of distribution or gain, and to any taxable years in the U.S. Holder's holding period prior to the first taxable year in which the Company was treated as a PFIC, would be treated as ordinary income; and
- the amount of the excess distribution or recognized gain allocated to each other taxable year would be subject to the highest tax rate in effect for individuals or corporations, as applicable, for each such year and the resulting tax will be subject to the interest charge generally applicable to underpayments of tax.

If the Company were a PFIC for any taxable year during which a U.S. Holder holds ADSs and any of our non-U.S. subsidiaries or other corporate entities in which we own equity interests is also a PFIC, the U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of each such non-U.S. entity classified as a PFIC, each such entity referred to as a lower-tier PFIC, for purposes of the application of these rules. U.S. Holders should consult their own tax advisor regarding the application of the PFIC rules to any of the Company's lower-tier PFICs.

If the Company were a PFIC for any taxable year during which a U.S. Holder holds ADSs, then in lieu of being subject to the tax and interest-charge rules discussed above, the U.S. Holder may make an election to include gain on the ADSs as ordinary income under a mark-to-market method, provided that our ADSs constitute "marketable stock." Marketable stock is stock that is regularly traded on a qualified exchange or other market, as defined in applicable Treasury Regulations. The Company expects that the ADSs, but not our shares, will be listed on the Nasdaq Global Select Market, which is a qualified exchange or other market for these purposes.

Consequently, if the ADSs are listed on the Nasdaq Global Select Market and are regularly traded, we expect that the mark-to-market election would be available to U.S. Holders of ADSs if the Company were to become a PFIC, but no assurances are given in this regard.

Because a mark-to-market election cannot be made for any lower-tier PFICs that the Company may own (unless the shares in such lower-tier PFIC are themselves treated as marketable stock), if the Company were a PFIC for any taxable year, a U.S. Holder that makes the mark-to-market election may continue to be subject to the tax and interest charges under the general PFIC rules with respect to such U.S. Holder's indirect interest in any investments held by the Company that are treated as an equity interest in a PFIC for U.S. federal income tax purposes.

In certain circumstances, a shareholder in a PFIC may avoid the adverse tax and interest-charge regime described above by making a "qualified electing fund" election to include in income its share of the corporation's income on a current basis. However, a U.S. Holder may make a qualified electing fund election with respect to the ADSs only if the Company agrees to furnish such U.S. Holder annually with a PFIC annual information statement as specified in the applicable Treasury Regulations. There is no assurance that we will provide such information that would enable a U.S. Holder to make a qualified electing fund election.

If a U.S. Holder owns ADSs during any year in which the Company is a PFIC, such U.S. Holder (including, potentially, indirect holders) generally will be required to file an IRS Form 8621 with such holder's U.S. federal income tax return for that year. U.S. Holders should consult their own tax advisors regarding the application of the PFIC rules to their ownership of the ADSs.

# Information Reporting and Backup Withholding

Dividend payments with respect to the ADSs and proceeds from a sale, exchange, redemption or other taxable disposition of the ADSs made within the United States or through certain U.S. related financial intermediaries may be subject to information reporting to the IRS and possible U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder that furnishes a correct taxpayer identification number and makes any other required certification on IRS Form W-9 or that is otherwise exempt from backup withholding. U.S. Holders of the ADSs should consult their tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against such U.S. Holder's U.S. federal income tax liability, and such holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing an appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

Certain U.S. Holders may be required to comply with certain reporting requirements relating to the ADSs, including filing IRS Form 8938, with respect to the holding of certain foreign financial assets, including stock of foreign issuers (such as the Company), either directly or through certain foreign financial institutions, if the aggregate value of all such assets exceeds U.S. \$50,000 on the last day of the tax year or U.S. \$75,000 at any time during the tax year. U.S. Holders who fail to report the required information could be subject to substantial penalties. U.S. Holders should consult their own tax advisors regarding the application of these rules to their ownership of the ADSs.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE IMPORTANT TO YOU. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ADSS.

#### Material Danish Income Tax Considerations

The following is a summary of material Danish tax considerations relating to the ownership and disposition of ADSs. The summary is for general information purposes only and does not constitute exhaustive tax or legal advice.

It is noted specifically that the summary does not address all possible tax consequences relating to the ownership and disposition of ADSs. The summary does accordingly not apply to investors to whom special tax rules apply, and, therefore, may not be relevant, for example, to investors subject to the Danish Tax on Pension Yields Act (i.e., pension savings), professional investors, certain institutional investors, insurance companies, pension companies, banks, stockbrokers and investors with tax liability on return on pension investments. The summary does further not apply to non-Danish tax resident investors that carry on business activities in Denmark through a permanent establishment.

*In the context of the following section, "companies" mean entities that are treated as separate taxable entities under domestic tax laws of their jurisdiction of incorporation.* 

The summary is based solely on the tax laws of Denmark in effect on the date of this Annual Report. Danish tax laws may be subject to change, potentially with retroactive effect.

Potential investors in the ADSs are advised to consult their tax advisors regarding the applicable tax consequences of ownership and disposition of the ADSs based on their particular circumstances.

# Tax Treatment of ADSs Under Danish Tax Law

It is currently not clear under Danish tax legislation or case law how ADSs are to be treated for Danish tax purposes. This summary assumes that the ADS holder in respect of the ADSs is treated as the direct owner of the shares underlying the ADSs and accordingly as the shareholder for Danish domestic tax law purposes, and that the ADS holder is deemed the beneficial owner of any dividend distributed on the underlying shares for Danish domestic tax law purposes as well as under any applicable tax treaty. Accordingly, the following deals with material Danish tax considerations relating to the ownership and disposition of listed shares.

#### **Danish Tax Resident Individuals**

# Sale of Shares

Capital gains from the sale of shares realized by Danish tax resident individuals are taxed as share income at a rate of 27% on the first DKK 56,500 (for cohabiting spouses, a total of DKK 113,000) and at a rate of 42% on share income exceeding DKK 56,500 (for cohabiting spouses over DKK 113,000) (all 2021 amounts and thresholds). The threshold is subject to annual adjustments and include all share income included in the calculation (*i.e.*, all capital gains on shares and dividends derived by the individual or cohabiting spouses, respectively).

Gains and losses on the sale of shares are calculated as the difference between the purchase price and the sales price. The purchase price is based on the average purchase price paid for the shares in the company (*i.e.*, not the purchase price paid for each share).

Losses on the sale of listed shares can only be offset against other share income deriving from listed shares (*i.e.*, dividends and capital gains on the sale of listed shares) and subject to the Danish tax authorities having received certain information concerning the ownership of the shares in due time. Unused losses will automatically be offset against a cohabiting spouse's share income deriving from listed shares and any additional losses can be carried forward and offset against future share income deriving from listed shares.

#### Dividends

Dividends paid to Danish tax resident individuals are included in the individual's share income and taxed as such, as outlined above. Dividends paid to Danish tax resident individuals are generally subject to withholding tax at the rate of 27%

# Non-Danish Tax Resident Individuals

# Sale of Shares

Non-Danish tax resident individuals, including individuals tax resident in the United States, are generally not taxed in Denmark on gains realized on the sale of shares, subject to certain anti-avoidance rules (see below).

# Dividends

Dividends paid to non-Danish tax resident individuals, including individuals tax resident in the United States, are generally subject to withholding tax at the rate of 27%. No additional tax will be imposed.

In the event that the shareholder is tax resident in a state with which Denmark has entered into a tax treaty and is entitled to benefits under such tax treaty, the shareholder may seek a refund from the Danish Tax Agency of the tax withheld in excess of the applicable treaty rate (Danish tax treaties typically provide for a 15% tax rate). Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all EU member states. The treaty between Denmark and the United States generally provides for a 15% tax rate.

Similarly, Danish domestic tax law provides for a 15% tax rate, if the shareholder holds less than 10% of the nominal share capital in the company and is tax resident in a state that is obligated to exchange information with Denmark under a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters. If the shareholder is tax resident outside the EU, it is an additional requirement for application of the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the share capital of the company.

Any reduced tax rate according to an applicable tax treaty and/or Danish domestic tax law will not affect the withholding rate (27%). In order to receive a refund (from 27% to *e.g.*, 15%), the shareholder must make a claim for such refund through certain certification procedures.

As a general rule, the refund shall be paid within six months following the Danish Tax Agency's receipt of the refund claim. If the refund is paid later than six months after the receipt of the claim, interest will in general be calculated on the amount of refund. For 2016 and subsequent years, the rate per month will be 0.4% plus a premium fixed annually. The sixmonth deadline is suspended by the Danish Tax Agency, if the Tax Agency is unable to determine whether the taxpayer is entitled to a refund based on the taxpayer's affairs. If the deadline is suspended accordingly, computation of interest is also suspended.

The Danish Tax Agency has published guidance on the documentation necessary for processing refund claims. The guidance is available in English from the Danish tax authorities' website, https://skat.dk. The information on, or information that can be accessed through, such website is not part of and should not be incorporated by reference into this Annual Report. We have included such website address as an inactive textual reference only.

# **Danish Tax Resident Companies**

Sale of Shares

For the purpose of taxation of sales of shares made by corporate shareholders (and dividends received by corporate shareholders, see below), a distinction is made between:

"Subsidiary Shares," which are generally defined as shares owned by a shareholder holding at least 10% of the share capital of the issuing company;

"Group Shares," which are generally defined as shares in a company in which the shareholder of the company and the issuing company are subject to Danish joint taxation or satisfy the requirements for international joint taxation under Danish law;

"Tax-Exempt Portfolio Shares," which are generally defined as unlisted shares owned by a shareholder holding less than 10% of the share capital of the issuing company; and

"Taxable Portfolio Shares," which are defined as shares that do not qualify as Subsidiary Shares, Group Shares or Tax-Exempt Portfolio Shares.

Gains and losses on disposal of Subsidiary Shares, Group Shares and Tax-Exempt Portfolio Shares realized by Danish tax resident companies are generally not included in the taxable income of the shareholder, subject to certain anti-avoidance rules (see below).

Capital gains on listed Taxable Portfolio Shares are taxable at the general corporate tax rate of 22% and losses on such shares are generally deductible. Gains and losses on listed Taxable Portfolio Shares are taxed under the mark-to-market principle irrespective of realization.

### Dividends

Dividends received on Subsidiary Shares and Group Shares are generally tax-exempt, subject to certain anti-avoidance rules (see below).

Dividends received on Taxable Portfolio Shares are taxable at the general corporate tax rate of 22% and tax is generally withheld similarly at 22%.

# Non-Danish Tax Resident Companies

Sale of Shares

Non-Danish tax resident companies, including companies tax resident in the United States, are generally not taxed in Denmark on gains realized on the sale of shares, subject to certain anti-avoidance rules (see below).

#### Dividends

Dividends received on Subsidiary Shares are exempt from Danish withholding tax provided that taxation shall be waived or reduced under the Parent-Subsidiary Directive (2011/96/EU) or under an applicable tax treaty. Similarly, dividends received on Group Shares, which are not Subsidiary Shares, are exempt from Danish withholding tax if the shareholder is resident in the EU or the EEA and provided that taxation shall be waived or reduced under the Parent-Subsidiary Directive (2011/96/EU) or under an applicable tax treaty had the shares been Subsidiary Shares.

In other cases, dividends will generally be subject to tax at a rate of 22% effective for dividends distributed on or after July 1, 2016. However, the withholding rate is 27%, meaning that all foreign corporate shareholders receiving taxable dividends distributed from Danish companies on or after July 1, 2016 will be able to ask for a refund of at least 5% of the total dividend.

Further, in the event that the shareholder is tax resident in a state with which Denmark has entered into a tax treaty and is entitled to the benefits under such tax treaty, the shareholder may seek a refund from the Danish Tax Agency of the tax withheld in excess of the applicable treaty rate (Danish tax treaties typically provide for a 15% tax rate). Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all EU member states. The treaty between Denmark and the United States generally provides for a 15% tax rate.

Similarly, Danish domestic tax law provides for an applicable 15% tax rate, if the shareholder holds less than 10% of the share capital in the company and is tax resident in a state that is obligated to exchange information with Denmark under a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters. If the shareholder is tax resident outside the EU, it is an additional requirement for eligibility for the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the nominal share capital of the company.

Any reduced tax rate according to an applicable tax treaty (and/or the 15% tax rate provided for under Danish domestic tax law) will not affect the withholding rate (27%). In order to receive a refund (from 27% to *e.g.*, 15%), the shareholder must make a claim for such refund through certain certification procedures.

As a general rule, the refund shall be paid within six months following the Danish Tax Agency's receipt of the refund claim. If the refund is paid later than six months after the receipt of the claim, interest will be calculated on the amount of refund. For 2016 and subsequent years, the rate per month will be 0.4% plus a premium fixed annually. The six-month deadline can be suspended by the Danish Tax Agency, if the Tax Agency is unable to determine whether the taxpayer is entitled to a refund based on the taxpayer's affairs. If the deadline is suspended accordingly, computation of interest is also suspended.

The Danish Tax Agency has published guidance on the documentation necessary for processing refund claims. The guidance is available in English from the Danish tax authorities' website, https://skat.dk. The information on, or information that can be accessed through, such website is not part of and should not be incorporated by reference into this Annual Report. We have included such website address as an inactive textual reference only.

### **Danish Anti-Avoidance Rules**

Payments may be subject to Danish withholding tax irrespective of the above, if the ADS holder is not the beneficial owner of the shares and dividend (e.g., if the ADS holder reassigns the payments to a person or entity not itself entitled to the above exemptions).

Further, Danish law has certain general anti-avoidance rules ("GAAR"), which focus on substance over form. Under these rules the Danish tax authorities can set aside a setup, which, having been put into place for the main purpose or one of the main purposes of obtaining a tax advantage that defeats the object or purpose of the applicable tax law, is not genuine having regard to all relevant facts and circumstances. Subject to the conditions of the GAAR an investor might be denied the benefits of the Parent-Subsidiary Directive (2011/96/EU) or a tax treaty, and Danish withholding tax of 27% will in such cases be levied.

Finally, it should be noted that it is the shareholder who owns the share, i.e., the ADS, at the time of the general meeting where the decision to distribute dividend is passed who is shareholder, who is subject to Danish taxation on the dividend, and thereby is entitled to make a tax reclaim if any.

# F. Dividends and Paying Agents

Not applicable.

# G. Statement by Experts

Not applicable.

# H. Documents on Display

Copies of this Annual Report on Form 20-F, as well as our Annual Report 2020, which includes our Audited Financial Statements, can be downloaded from the "Investors" page at www.genmab.com. The contents of our website are not incorporated by reference into this Annual Report on Form 20-F. This Annual Report on Form 20-F is also filed and can be viewed via EDGAR on www.sec.gov.

# I. Subsidiary Information

Not applicable.

# ITEM 11 QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISKS

For qualitative and quantitative disclosures about market risks including foreign currency risk interest rate risk, and credit risk, see Note 4.2 to our Audited Financial Statements included in our Annual Report 2020.

# ITEM 12 DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

# A. Debt Securities

Not applicable.

# B. Warrants and Rights

Not applicable.

### C. Other Securities

Not applicable.

# D. American Depositary Shares

Genmab's ADS program is administered by Deutsche Bank Trust Company Americas, as depositary. The principal executive office of the depositary is located at 60 Wall Street, New York, NY 10005, USA. Below is a summary of fees and expenses payable by ADS holders and of fees and payments by the depositary to us. Please refer to Exhibit 2.3 hereto for a summary of certain other material provisions of the amended and restated deposit agreement related to our ADS program. For more complete information, holders should read the entire amended and restated deposit agreement and the form of American Depositary Receipt incorporated by reference as Exhibit 2.1 and 2.2 hereto, respectively.

## Fees and Expenses

ADS holders will be required to pay the following service fees to the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of their ADSs):

	Service	Fees
•	To any person to which ADSs are issued or to any person to which a distribution is made in respect of ADS distributions pursuant to stock dividends or other free distributions of stock, bonus distributions, stock splits or other distributions (except where converted to cash)	Up to \$0.05 per ADS issued
•	Cancellation of ADSs, including the case of termination of the deposit agreement	Up to \$0.05 per ADS cancelled
•	Distribution of cash dividends	Up to \$0.05 per ADS held
•	Distribution of cash entitlements (other than cash dividends) and/or cash proceeds from the sale of rights, securities and other entitlements	Up to \$0.05 per ADS held
•	Distribution of ADSs pursuant to exercise of rights.	Up to \$0.05 per ADS held
•	Distribution of securities other than ADSs or rights to purchase additional ADSs	Up to \$0.05 per ADS held
•	Depositary services	Up to \$0.05 per ADS held on the applicable record date(s) established by the depositary bank

ADS holders will also be responsible to pay certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of their ADSs) such as:

- fees for the transfer and registration of shares charged by the registrar and issuing agent for the shares in the Kingdom of Denmark (i.e., upon deposit and withdrawal of shares);
- expenses incurred for converting foreign currency into U.S. dollars;
- expenses for cable, telex and fax transmissions and for delivery of securities;
- taxes and duties upon the transfer of securities, including any applicable stamp duties, any stock transfer charges or withholding taxes (i.e., when shares are deposited or withdrawn from deposit);
- fees and expenses incurred in connection with the delivery or servicing of shares on deposit;

- fees and expenses incurred in connection with complying with exchange control regulations and other regulatory requirements applicable to shares, deposited securities, ADSs and ADRs; and
- any applicable fees and penalties thereon.

The depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary bank by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary bank and by the brokers (on behalf of their clients) delivering the ADSs to the depositary bank for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary bank to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed or by selling a portion of distributable property to pay the fees. In the case of distributions other than cash (*i.e.*, share dividends, rights), the depositary bank charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary bank sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via the Depositary Trust Company ("DTC")), the depositary bank generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary banks.

In the event of refusal to pay the depositary fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

### Fees and Payments by the Depositary to Us

The depositary may make payments to us or reimburse us for certain costs and expenses, by making available a portion of the ADS fees collected in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

# PART II

# ITEM 13 DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

# ITEM 14 MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

# ITEM 15 CONTROLS AND PROCEDURES

# **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a- 15(e) and 15d- 15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 20-F. Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2020.

# Report of Genmab Management on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS as issued by the IASB.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2020, using the criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment our management concluded that, as of December 31, 2020, Genmab's internal control over financial reporting was effective based on criteria stated in Internal Control – Integrated Framework (2013) issued by the COSO.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2020 has been audited by PricewaterhouseCoopers, Statsautoriseret Revisionspartnerselskab, Denmark, an independent registered public accounting firm, as stated in their report which appears on page 129 of this Annual Report.

# **Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

# ITEM 16A AUDIT COMMITTEE FINANCIAL EXPERTS

Our Audit and Finance Committee consists of members Jonathan Peacock, Rolf Hoffmann and Deirdre P. Connelly and is chaired by Pernille Erenbjerg. Each member of the Audit and Finance Committee satisfies the independence requirements of the corporate governance standards of the Nasdaq Stock Market, and Pernille Erenbjerg qualifies as an "audit committee financial expert," as defined in Nasdaq Rule 5605(c)(2)(A) and as determined by our Board of Directors.

# ITEM 16B CODE OF ETHICS

We have adopted a written Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our directors and employees. This document is available under the "Corporate Governance" tab on the "Investors" page of our website (www.genmab.com). The contents of this website are not incorporated by reference into this Annual Report on Form 20-F.

During 2020, the Company did not significantly amend its Code of Conduct or grant any waiver, including any implicit waiver, from any provision of the Code of Conduct to any of its directors or employees. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

# ITEM 16C PRINCIPAL ACCOUNTANT FEES AND SERVICES

For principal accountant fees and services, see Note 5.6 to our Audited Financial Statements included in our Annual Report 2020.

#### **Audit Fees**

Audit fees consist of fees billed for professional services rendered by the principal accountant for the audit of the registrant's annual financial statements or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for those fiscal years.

### **Audit-Related Fees**

Audit-Related fees consist of assurance and related services by the principal accountant that are reasonably related to the performance of the audit or review of the registrant's financial statements and are not reported under "Audit Fees". Fees for audit-related services include consultations concerning financial accounting reporting standards.

### Tax Fees

Tax fees consist of fees billed for professional services rendered by the principal accountant for tax compliance, tax advice, and tax planning, including tax fees billed for tax consultations.

#### All Other Fees

All other fees consist of products and services provided by the principal accountant, other than the services reported in "Audit Fees," "Audit-Related Fees" and "Tax Fees".

Fees for other services comprise fees billed for other permitted services, primarily related to Genmab's initial public offering and listing of ADSs on the Nasdaq in the United States.

# **Pre-Approval Policies**

The Audit Committee assesses and pre-approves all audit and non-audit services provided by the statutory auditors.

### ITEM 16D EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

# ITEM 16E PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

# ITEM 16F CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

None.

# ITEM 16G CORPORATE GOVERNANCE

The listing rules of the Nasdaq (the "Nasdaq Listing Rules") provide that foreign private issuers may follow home country practice in lieu of Nasdaq Global Select Market corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws. The home country practices we follow in lieu of the Nasdaq Listing Rules are described below.

• We do not follow the quorum requirements of the Nasdaq Stock Market applicable to meetings of shareholders. In accordance with Danish corporate law and generally accepted business practice, our articles of association do not provide quorum requirements for general meetings of shareholders.

- We do not follow the requirements of the Nasdaq Stock Market regarding the provision of proxy statements for general meetings of shareholders. Danish corporate law does not have a regulatory regime for the solicitation of proxies. The solicitation of proxies is not a generally accepted business practice in Denmark, although it has recently become more common for listed companies to do so. However, a shareholder may be represented at a general meeting by proxy. Unless containing a provision to the contrary, instruments of proxy will be deemed to be in force until revoked in writing by notification to the company. Rather than providing proxy statements, we provide notice convening a general meeting, including an agenda and other relevant documents, to the Danish Business Authority and written notice to all registered shareholders who have so requested.
- We do not follow the requirements of the Nasdaq Stock Market regarding shareholder approval for certain issuances of securities under Nasdaq Listing Rule 5635. Pursuant to Danish corporate law and our articles of association, our shareholders have authorized our Board to issue securities, including shares and warrants.
- We do not follow the requirement of the Nasdaq Stock Market that each member of the Compensation Committee be independent as defined under Nasdaq Listing Rule 5605(a)(2). No such requirement exists pursuant to Danish law. We do not have an independent Compensation Committee within the meaning of the Nasdaq Listing Rules because we consider Anders Gersel Pedersen, a member of the Compensation Committee, to be a non-independent director solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. We do not consider Dr. Pedersen's tenure as material to his ability to be independent from senior management in connection with his duties as a Compensation Committee member. The charter of the Compensation Committee requires a majority of its members to be independent.
- We do not follow the requirement of the Nasdaq Stock Market that we have independent director oversight of director nominations as prescribed by Nasdaq Listing Rule 5605(e)(1). No such requirement exists pursuant to Danish law. We do not have independent oversight of director nominations because we consider Anders Gersel Pedersen, Chairman of the Nominating and Corporate Governance Committee, to be a non-independent director solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. We do not consider Dr. Pedersen's tenure as material to his ability to be independent from senior management in connection with his duties as Chairman of the Nominating and Corporate Governance Committee. The charter of the Nominating and Corporate Governance Committee requires a majority of its members to be independent.
- We do not follow the requirement of the Nasdaq Stock Market that our independent directors must have regularly scheduled meetings at which only independent directors are present. No such requirement exists pursuant to Danish law. Our directors regularly meet in executive sessions without the participation of management. However, our Employee Elected Directors, who are not independent within the meaning of the Nasdaq Listing Rules, attend these executive sessions.

# ITEM 16H MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17 FINANCIAL STATEMENTS

See "Item 18—Financial Statements."

# **ITEM 18 FINANCIAL STATEMENTS**

The financial statements required by this item are incorporated herein by reference to pages 85-131 of our Annual Report 2020.

# **ITEM 19 EXHIBITS**

# a. Annual Report

The following pages from our Annual Report 2020, furnished to the SEC as Exhibit 99.1(a) to Form 6-K, dated February 23, 2021, are incorporated by reference into this Form 20-F. The content of websites, scientific articles and other sources referenced on these pages are not incorporated by reference into this Annual Report on Form 20-F.

# Page(s) incorporated by reference from our Annual Report 2020

Financial Review - pages 63-68

Consolidated Financial Statements for the Genmab Group – pages 85-131

Consolidated Statements of Comprehensive Income for the years ended December 31, 2020, 2019 and 2018 – page 87

Consolidated Balance Sheets as of December 31, 2020 and 2019 – page 88

Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018 - page 89

Consolidated Statements of Changes in Equity for the years ended December 31, 2020, 2019 and 2018 - page 90

Notes to the Consolidated Financial Statements – pages 91-131

### b. Exhibits

# **Exhibit Index**

Exhibit No.	Description	Method of filing
1.1	English translation of Articles of Association of Genmab A/S, as currently in effect	Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on March 3, 2021
2.1	Amended and Restated Deposit Agreement	Incorporated by reference to Exhibit (a)(3) to the Registrant's Form F-6 filed with the SEC on July 15, 2019
2.2	Form of American Depositary Receipt	Included in Exhibit 2.1, which is incorporated by reference to Exhibit (a)(3) to the Registrant's Form F-6 filed with the SEC on July 15, 2019
2.3	$\underline{\text{Description of Securities Registered under Section 12 of the Exchange}} \\ \underline{\text{Act}}$	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2019
4.1†	<u>License Agreement, dated as of August 30, 2012, by and between Janssen Biotech, Inc. and Genmab A/S</u>	Incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.2†	Amendment Number 1 to the License Agreement, dated as of January 31, 2013, by and between Janssen Biotech, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019

xhibit No.	Description	Method of filing
4.3†	Amendment Number 2 to the License Agreement, dated as of October 10, 2013, by and between Janssen Biotech, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.3 to the Registrant' registration statement on Form F-1/A filed with the SEC or July 16, 2019
4.4†	<u>License and Collaboration Agreement, dated as of October 7, 2011, by and between Seagen, Inc. and Genmab A/S</u>	Incorporated by reference to Exhibit 10.4 to the Registrant' registration statement on Form F-1/A filed with the SEC or July 16, 2019
4.5†	Joint Commercialization Agreement dated October 19, 2020 between Genmab A/S and Seagen Inc.	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2020
4.6†	Co-development and Collaboration Agreement, dated as of December 19, 2006, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.5 to the Registrant' registration statement on Form F-1/A filed with the SEC or July 16, 2019
4.7†	Amendment Number 1 to the Co-development and Collaboration Agreement, dated as of June 30, 2008, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.6 to the Registrant' registration statement on Form F-1/A filed with the SEC or July 16, 2019
4.8†	Amendment Number 2 to the Co-development and Collaboration Agreement, dated as of December 18, 2008, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.7 to the Registrant registration statement on Form F-1/A filed with the SEC or July 16, 2019
4.9†	Amendment Number 3 to the Co-development and Collaboration Agreement, dated as of July 1, 2010, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.8 to the Registrant registration statement on Form F-1/A filed with the SEC of July 16, 2019
4.10†	Amendment Number 4 to the Co-development and Collaboration Agreement, dated as of December 20, 2010, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.9 to the Registrant registration statement on Form F-1/A filed with the SEC of July 16, 2019
4.11†	Novation Agreement, dated as of November 3, 2014, by and among Glaxo Group Limited, Novartis Pharma AG and Genmab A/S	Incorporated by reference to Exhibit 10.10 to the Registrar registration statement on Form F-1/A filed with the SEC of July 16, 2019
4.12†	Amendment Number 5 to the Co-development and Collaboration Agreement, dated as of January 22, 2018, by and between Novartis Pharma AG and Genmab A/S	Incorporated by reference to Exhibit 10.11 to the Registrar registration statement on Form F-1/A filed with the SEC o July 16, 2019
4.13†	Amended and Restated Evaluation and Commercialization Agreement, dated as of July 12, 2012, by and among BristolMyer Squibb Corporation, Medarex, Inc., GenPharm International, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.12 to the Registrar registration statement on Form F-1/A filed with the SEC o July 16, 2019
4.14†	Collaboration and License Agreement, dated as of June 10, 2020 by and between AbbVie Biotechnology Ltd. and Genmab A/S	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2020
8.1	List of Subsidiaries	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2020
12.1	Certification of the Principal Executive Officer	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2020
12.2	Certification of the Principal Financial Officer	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2020
13.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. section 1350	Furnished together with this Annual Report on Form 20-F the year ended December 31, 2020
13.2	<u>Certification of the Principal Financial Officer pursuant to 18 U.S.C.</u> <u>section 1350</u>	Furnished together with this Annual Report on Form 20-F the year ended December 31, 2020
15.1	Consent of Independent Registered Public Accounting Firm	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2020

Exhibit No.	Description	Method of filing
EX-101.INS	XBRL Instance Document	Incorporated by reference to Exhibit 101.INS to the Registrant's report furnished to the SEC on Form 6-K on February 23, 2021
EX-101.SCH	XBRL Taxonomy Extension Schema Document	Incorporated by reference to Exhibit 101.SCH to the Registrant's report furnished to the SEC on Form 6-K on February 23, 2021
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Incorporated by reference to Exhibit 101.CAL to the Registrant's report furnished to the SEC on Form 6-K on February 23, 2021
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Incorporated by reference to Exhibit 101.DEF to the Registrant's report furnished to the SEC on Form 6-K on February 23, 2021
EX-101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	Incorporated by reference to Exhibit 101.LAB to the Registrant's report furnished to the SEC on Form 6-K on February 23, 2021
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Incorporated by reference to Exhibit 101.PRE to the Registrant's report furnished to the SEC on Form 6-K on February 23, 2021

Portions of this exhibit, marked by brackets, have been omitted pursuant to Instruction 4(a) to Exhibits to Form 20-F because they are both (i) not material and (ii) include information of the type that we treat as private or confidential.

# **SIGNATURES**

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

Genmab A/S

/s/ Jan G. van de Winkel

Name: Jan G. van de Winkel

Title: President and Chief Executive Officer

Dated: March 29, 2021

# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Genmab A/S

### Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the consolidated balance sheets of Genmab A/S and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of comprehensive income, of changes in equity and of cash flow for each of the three years in the period ended December 31, 2020, including the related notes, as listed in the index appearing under Item 19a (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

### **Basis for Opinions**

The Company's Management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the Report of Genmab Management on Internal Control over Financial Reporting appearing under Item 15. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by Management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

# Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately

and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorisations of Management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorised acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

#### **Critical Audit Matters**

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition on the AbbVie collaboration agreement

As described in Note 2.1 to the consolidated financial statements, on June 10, 2020 Genmab entered into a collaboration agreement with AbbVie Inc. to jointly develop and commercialize epcoritamab (DuoBody-CD3xCD20), DuoHexaBody-CD37 and DuoBody-CD3x5T4 and a discovery research collaboration for future differentiated antibody therapeutics for cancer. The agreement includes four performance obligations: delivery of three licenses and codevelopment activities for product concepts. During 2020, Genmab received an upfront payment of DKK 4,911 million and allocated DKK 4,398 million to the delivery of the licenses and DKK 513 million to the co-development activities for product concepts. Genmab recognised revenue of DKK 4,398 million from the delivery of licenses when the performance obligation was satisfied at a point in time for these.

The principal considerations for our determination that performing procedures relating to revenue recognition on the AbbVie collaboration agreement is a critical audit matter are that identifying performance obligations and allocating the transaction price between these performance obligations based on a best accounting estimate of relative stand-alone selling price and determining whether the performance obligations have been satisfied requires significant judgment by Management. This in turn led to significant auditor judgment, effort and subjectivity, in applying procedures relating to these judgments. In addition, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the process to record revenue, including controls related to the identification of the performance obligations, allocation of transaction price and if the performance obligations were satisfied. These procedures also included, among others, examination of the collaboration agreement and evaluation and testing of Management's assessment of the nature of the performance obligations, allocating the transaction price between these performance obligations and whether these were satisfied. This included (i) assessing the nature of the performance obligations; (ii) involving professionals with specialised skill and knowledge to assist in assessing the model, data and assumptions used in estimating the stand-alone selling price; and (iii) assessing whether the performance obligations were satisfied upon the transfer of licenses.

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/s/ PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab Hellerup, Denmark March 29, 2021

We have served as the Company's auditor since 2000.

### DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

Genmab A/S ("Genmab" or the "Company") had the following securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934 (the "Exchange Act"):

Trading symbol	Name of each exchange on which registered
GMAB	The NASDAQ Global Select Market
GMAB	The NASDAQ Global Select Market*
	GMAB

<sup>\*</sup> Not for trading, but only in connection with the registration of the American Depositary Shares on The NASDAQ Global Select Market.

This exhibit contains a description of the rights of (i) the holders of ordinary shares and (ii) the holders of ADSs. The following summary is subject to and qualified in its entirety by Genmab's articles of association (the "Articles of Association") and by applicable Danish law, particularly the Danish Companies Act (*Selskabsloven*) (the "DCA"). This is not a summary of all the significant provisions of the Articles of Association or of Danish law and does not purport to be complete. Capitalized terms used but not defined herein have the meanings given to them in the Company's annual report on Form 20-F to which this description of securities registered under section 12 of the Exchange Act (the "Description of Securities") is an exhibit and in the form of Amended and Restated Deposit Agreement (the "Deposit Agreement"), filed as Exhibit (a)(3) to Genmab's registration statement on Form F-1 filed with the SEC on July 16, 2019.

### **ORDINARY SHARES**

#### Item 9. General

# Item 9.A.3 Pre-emptive rights

*Denmark.* As a general rule, shareholders of the Company are entitled to subscribe for new shares in proportion to their existing shareholdings in the event of a cash increase of the share capital. Such a cash increase of the share capital can be resolved by the general meeting by at least two-thirds of the votes cast as well as at least two-thirds of the share capital represented at the general meeting.

However, in the below-mentioned scenarios, the general meeting may resolve to depart from the shareholders' right to proportionate subscription if the following voting requirements are met:

- two-thirds majority requirement: if the new shares issued in connection with the capital increase are subscribed for at
  market price for the benefit of some of the existing shareholders, the above-mentioned two-thirds majority requirement
  applies;
- consent requirement: if the new shares issued in connection with the capital increase are subscribed for at a discount for the benefit of some of the existing shareholders, consent from the shareholders who do not get an opportunity to participate in the capital increase must be obtained;
- two-thirds majority requirement: if the new shares issued in connection with the capital increase are subscribed for at market price for the benefit of parties other than the existing shareholders (*i.e.*, a third party or employees of the company), the above-mentioned two-thirds majority requirement applies; and
- nine-tenths majority requirement: if the new shares issued in connection with the capital increase are subscribed for at discount for the benefit of parties other than the existing shareholders or the employees of the company, the voting requirement is at least nine-tenths of the votes cast as well as at least nine-tenths of the share capital represented at the general meeting.

The board of directors may resolve to increase Genmab's share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations currently in force.

Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights under U.S. securities law.

*Delaware*. Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

# Item 9.A.5 Type and class of securities

The Company's ordinary shares are listed on the Nasdaq Copenhagen and are registered under Section 12(b) of the Exchange Act in connection with the listing of the Company's ADSs (but not for trading) and have a nominal value of DKK 1 per share. All ordinary shares are issued in registered form.

# Item 9.A.6 Limitations or qualifications

Not applicable.

Item 9.A.7 Other rights

Not applicable.

Item 10.B Memorandum and articles of association

Item 10.B.3 Shareholder rights

Dividends

Denmark. Under Danish law, the distribution of ordinary and interim dividends requires the approval of a company's shareholders at a company's general meeting. In addition the shareholders may authorize the board of directors to distribute interim dividends. The shareholders may not resolve to the distribution of dividends in excess of the recommendation from the board of directors and Genmab may only pay out dividends from Genmab's distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward. It is possible under Danish law to pay out interim dividends. The decision to pay out interim dividends shall be accompanied by a balance sheet, and the board of directors determines whether it will be sufficient to use the statement of financial position from the annual report or if an interim statement of financial position for the period from the annual report period until the interim dividend payment shall be prepared. If interim dividends are paid out later than six months following the end of the financial year for the latest annual report, an audited interim balance sheet showing that there are sufficient funds shall always be prepared.

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of shares, property or cash.

# **Voting Rights**

Pursuant to the Articles of Association, each share with a nominal value of DKK 1 carries one vote at general meetings.

*Denmark.* Each share confers the right to cast one vote at the general meeting of shareholders, unless the Articles of Association provide otherwise. Each holder of shares may cast as many votes as it holds shares. Shares that are held by Genmab or its direct or indirect subsidiaries do not confer the right to vote.

*Delaware*. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or

the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

# **Adoption of Shareholder Resolutions**

All resolutions put to the vote of shareholders at general meetings are subject to adoption by a simple majority of votes, unless the DCA or the Articles of Association prescribes other requirements.

# **Notice of Meeting**

*Denmark.* According to the DCA and as implemented in the Articles of Association, general meetings in listed limited liability companies shall be convened by the board of directors with a minimum of three weeks' notice and a maximum of five weeks' notice. A convening notice shall also be forwarded to shareholders recorded in Genmab's shareholders' register who have requested such notification. There are specific requirements as to the information and documentation required to be disclosed in connection with the convening notice.

*Delaware*. Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour and purpose or purposes of the meeting.

# **Shareholder Proposals**

*Denmark.* According to the DCA, extraordinary general meetings of shareholders will be held whenever Genmab's board of directors or its appointed auditor requires. In addition, one or more shareholders each representing at least 5% of the registered share capital of the company may, in writing, require that a general meeting be convened. If such a demand is made, the board of directors shall convene the general meeting within two weeks thereafter (after providing three to five weeks notice).

All shareholders have the right to present proposals for adoption at the annual general meeting, provided that the proposals are submitted at least six weeks prior to the meeting. In the event that the request is made at a later date, the board of directors will determine whether the proposals were made in due time to be included on the agenda.

*Delaware*. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

# **Action by Written Consent**

*Denmark.* Under Danish law, shareholders may take action and pass resolutions by written consent if such consent is unanimous. However, for a listed company, this method of adopting resolutions is generally not feasible.

*Delaware*. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

# **Appraisal Rights**

*Denmark.* The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemption rights according to the DCA.

According to Section 73 of the DCA, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital and votes to redeem his or her shares. Similarly, a majority shareholder holding more than 90%

of the company's share capital and votes may, according to Section 70 of the DCA, squeeze out the minority shareholders. In the event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the DCA that require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger are, according to Sections 286 and 306 of the DCA, entitled to have their shares redeemed.

*Delaware.* The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

# **Shareholder Suits**

Denmark. Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. However, if shareholders representing at least 10% of the share capital have opposed at a general meeting a decision to grant discharge to a member of Genmab's board of directors or its registered managers or refrain from bringing law suits against, among other persons, a member of its board of directors or a registered manager, a shareholder may bring a derivative action on behalf of our company against, among other persons, a member of its board of directors or a registered manager. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

# **Inspection of Books and Records**

Denmark. According to Section 150 of the DCA, a shareholder may, at the annual general meeting or at a general meeting whose agenda includes such item, request an inspection of the Company's books regarding specific issues concerning the management of the Company or specific annual reports. If approved by shareholders with a simple majority, one or more investigators are elected. If the proposal is not approved by a simple majority but 25% of the share capital votes in favor of the proposal, then the shareholder can request the court to appoint an investigator, however, the request will only be allowed if the court finds it to be based on reasonable grounds.

*Delaware*. Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation's books and records, for any proper purpose, during the corporation's usual hours of business.

# Notice Convening Annual and Extraordinary General Meetings

General meetings shall be held in the municipality of Copenhagen or in the greater Copenhagen area (*Storkøbenhavn*). General meetings shall be convened by the board of directors giving not less than three weeks' and not more than five weeks' notice. General meetings shall be announced by notification to Nasdaq Copenhagen and through publication on our website. Furthermore, all shareholders registered in Genmab's shareholders' register who have so requested shall be notified by letter or email. The notice shall set out the time and place for the general meeting and the issues to be considered at the general meeting. If the general meeting is to consider a proposal to amend the Articles of Association, then the notice shall specify the material content of the proposal. The notice calling the general meeting as well as other documents prepared for and in connection with the general meeting shall be prepared in English and, if decided by Genmab's board of directors, also in Danish.

A shareholder's right to attend general meetings and to vote is determined on the basis of the shares that the shareholder owns on the registration date which date is one week before the general meeting is held.

Any shareholder shall be entitled to attend general meetings, provided he or she has requested an admission card from our offices not later than three days prior to the relevant meeting. The admission card will be issued to the shareholders registered in our shareholders' register. The shareholder may attend in person or be represented by proxy, and a shareholder shall be entitled to attend together with an advisor. A shareholder may vote by proxy or by mail, and a form for this use shall be made available on Genmab's

website no later than three weeks prior to the general meeting. A vote by mail must be received by Genmab not later than three days prior to the general meeting in order to be counted at the general meeting.

Extraordinary general meetings shall be held as directed by the shareholders at the general meeting, the board of directors or an auditor, or upon a written request to the board of directors by shareholders holding not less than 5% of the share capital for consideration of a specific issue. The general meeting shall be convened (after providing three to five weeks notice) within 14 days after the proper request has been received by Genmab's board of directors.

# **Shareholder Identification**

The EU has adopted an amendment to the shareholder rights directive, or Directive 2017/828. The amendment has been implemented in Denmark and entered into force on June 10, 2019. The main purpose of the rules is to strengthen shareholder participation in listed companies. Pursuant to these rules, Genmab may request from central security depositaries, or CSDs, depositaries and other intermediaries information about the identity of its shareholders and the number of shares, share class and date of acquisition of the shares held by its shareholders. The intermediaries will be required to transmit such requests on shareholder identification between them in order to provide Genmab with the requested information.

### Redemption provisions

No shareholder shall be obliged to let his shares be redeemed in full or in part by Genmab or by any other party, except as provided in the DCA.

# Rights to share in any surplus in the event of liquidation

If Genmab is liquidated, any assets remaining after payment of its debts, liquidation expenses and all of its remaining obligations will be distributed among shareholders proportionally to their shareholding in the Company.

# Item 10.B.4 Changes to shareholder rights

# Shareholder Vote on Certain Reorganizations

*Denmark.* Under Danish law, all amendments to the Articles of Association shall be approved by the general meeting of shareholders with a minimum of two-thirds of the votes cast and two-thirds of the share capital represented at the general meeting. The same applies to solvent liquidations, mergers with the company as the discontinuing entity, mergers with the company as the continuing entity if shares are issued in connection therewith and demergers. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company's business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required. However, under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

### **Amendments to Governing Documents**

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the DCA and the Articles of Association. Resolutions concerning all amendments to the Articles of Association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.

# **Item 10.B.6 Limitations**

There are no restrictions on the rights of non-resident or foreign shareholders to hold or exercise voting rights with respect to Genmab's shares.

# Item 10.B.7 Change in control

The Articles of Association do not contain any provisions that would have the effect of delaying, deferring or preventing a change in control of the Company and that would operate only with respect to a merger, acquisition or corporate restructuring involving the Company (or any of its subsidiaries).

# Item 10.B.8 Disclosure of shareholdings

Genmab's constitutional documents do not contain any provisions governing the ownership threshold above which shareholder ownership must be disclosed. However, pursuant to the DCA, public and private limited liability companies are required to register with the Danish Business Authority information regarding shareholders who own at least 5% of the share capital or the voting rights. Pursuant to this provision, Genmab files registrations with the Danish Public Shareholders' Register of the Danish Business Authority. Shareholders that exceed or fall below the ownership threshold must notify Genmab, and Genmab will subsequently file the information with the Danish Business Authority. Reporting is further required upon passing or falling below thresholds of 10%, 15%, 20%, 25%, 50%, 90%, and 100% as well as one third and two thirds of the votes or the share capital. This also applies to beneficial holders of Genmab's shares, such as holders of the ADSs.

### Item 10.B.9 Differences in the law

With respect to Items 10.B.2-10.B.8, Genmab has identified in the responses above where the Danish law applicable to Genmab is significantly different from the comparable Delaware law.

### Item 10.B.10 Changes in capital

The requirements imposed by the Articles of Association governing changes in capital are not more stringent than is required by law.

# AMERICAN DEPOSITARY SHARES

Item 12.A Debt securities

Not applicable.

**Item 12.B Warrants and Rights** 

Not applicable.

**Item 12.C Other securities** 

Not applicable.

**Item 12.D.1 Depositary** 

Deutsche Bank Trust Company Americas has been appointed as the depositary pursuant to the Deposit Agreement. The depositary's corporate office at which the ADSs are administered and the principal executive office is located at 60 Wall Street, New York, NY 10005, USA. Danske Bank A/S has been appointed as the custodian for the depositary.

# Item 12.D.2 Description of the ADSs

Genmab's ADSs are listed on the NASDAQ Global Select Market and traded under the symbol 'GMAB'. Each ADS represents ownership of one tenth of one ordinary share. Each ADS also represents ownership of any other securities, cash or other property which may be held by the depositary in respect of such shares.

The following is a summary of the material provisions of the Deposit Agreement. For more complete information, holders should read the Deposit Agreement in its entirety. The Deposit Agreement has been filed with the SEC as Exhibit 4.1 to the Company's registration statement on Form F-1 filed with the SEC on July 16, 2019.

### **Dividends and Other Distributions**

# **Receipt of Dividends and Other Distributions**

The depositary has agreed to pay to holders of the ADSs the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Holders will receive these distributions in proportion to the number of shares their ADSs represent as of the record date (which will be as close as practicable to the record date for Genmab's shares) set by the depositary with respect to the ADSs.

• Cash. The depositary will convert or cause to be converted any cash dividend or other cash distribution Genmab pays on the shares or any net proceeds from the sale of any shares, rights, securities or other entitlements under the terms of the Deposit Agreement into U.S. dollars if it can do so on a practicable basis, and can transfer the U.S. dollars to the United States and will distribute promptly the amount thus received. If the depositary shall determine in its judgment that such conversions or transfers are not practical or lawful or if any government approval or license is needed and cannot be obtained at a reasonable cost within a reasonable period or otherwise sought, the Deposit Agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold or cause the custodian to hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid and such funds will be held for the respective accounts of the ADS holders. It will not invest the foreign currency and it will not be liable for any interest for the respective accounts of the ADS holders.

Before making a distribution, any taxes or other governmental charges, together with fees and expenses of the depositary, that must be paid, will be deducted. See "Item 10—Material U.S. Federal Income Tax Considerations" and "Item 10—Material Danish Income Tax Considerations" in the annual report on Form 20-F to which this Description of Securities is an exhibit. It will distribute only whole U.S. dollars and cents and will round down fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, holders may lose some or all of the value of the distribution.

- Shares. For any shares Genmab distributes as a dividend or free distribution (such shares considered bonus shares under the DCA), either (1) the depositary will distribute additional ADSs representing such shares or (2) existing ADSs as of the applicable record date will represent rights and interests in the additional shares distributed, to the extent reasonably practicable and permissible under law, in either case, net of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The depositary will only distribute whole ADSs. It will try to sell shares which would require it to deliver a fractional ADS and distribute the net proceeds in the same way as it does with cash. The depositary may sell a portion of the distributed shares sufficient to pay its fees and expenses and any taxes and governmental charges in connection with that distribution.
- Elective Distributions in Cash or Shares. If Genmab offers Genmab's shareholders the option to receive dividends in either cash or shares (such shares considered bonus shares under the DCA), the depositary, after consultation with Genmab and having received timely notice as described in the Deposit Agreement of such elective distribution by Genmab, has discretion to determine to what extent such elective distribution will be made available to holders of the ADSs. Genmab must timely first instruct the depositary to make such elective distribution available to holders and furnish it with satisfactory evidence that it is legal to do so. However, the depositary could decide it is not legal or reasonably practicable to make such elective distribution available to holders. In such case, the depositary shall, on the basis of the same determination as is made in respect of the shares for which no election is made, distribute either cash in the same way as it does in a cash distribution, or additional ADSs representing shares in the same way as it does in a share distribution. The depositary is not obligated to make available to holders a method to receive the elective distribution in shares rather than in ADSs. There can be no assurance that holders will be given the opportunity to receive elective distributions on the same terms and conditions as Genmab's shareholders.
- *Rights to Purchase Additional Shares.* If Genmab offers its shareholders any rights to subscribe for additional shares, the depositary shall, having received timely notice as described in the Deposit Agreement of such distribution by

Genmab, consult with Genmab, and Genmab must determine whether it is lawful and reasonably practicable to make these rights available to holders. Genmab must first instruct the depositary to make such rights available to holders and furnish the depositary with satisfactory evidence that it is legal to do so. However, if the depositary decides it is not legal or reasonably practicable to make the rights available but that it is lawful and reasonably practicable to sell the rights, the depositary will endeavor to sell the rights and, in a riskless principal capacity or otherwise, at such place and upon such terms (including public or private sale) as it may deem proper distribute the net proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. In that case, holders will receive no value for them.

If the depositary makes rights available to holders, it will establish procedures to distribute such rights and enable holders to exercise the rights upon their payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The depositary shall not be obliged to make available to holders a method to exercise such rights to subscribe for shares (rather than ADSs).

U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, holders may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

There can be no assurance that holders will be given the opportunity to exercise rights on the same terms and conditions as Genmab's shareholders or be able to exercise such rights.

• Other Distributions. Subject to receipt of timely notice, as described in the Deposit Agreement, from Genmab with the request to make any such distribution available to holders, and provided the depositary has determined such distribution is lawful and reasonably practicable and feasible and in accordance with the terms of the Deposit Agreement, the depositary will distribute to holders anything else Genmab distributes on deposited securities by any means it may deem practicable, upon their payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. If any of the conditions above are not met, the depositary will endeavor to sell, or cause to be sold, the property Genmab distributed and distribute the net proceeds in the same way as it does with cash; or, if it is unable to sell such property, the depositary may dispose of such property in any way it deems reasonably practicable under the circumstances for nominal or no consideration, such that holders may have no rights to or arising from such property.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. Genmab has no obligation to register ADSs, shares, rights or other securities under the Securities Act. Genmab also has no obligation to take any other action to permit the distribution of ADSs, shares, rights or any other property to ADS holders. This means that holders may not receive the distributions Genmab makes on its shares or any value for them if Genmab and/or the depositary determines that it is illegal or not practicable for Genmab or the depositary to make them available to holders.

# **Deposit, Withdrawal and Cancellation**

# Cancellation

Holders may turn in their ADSs at the depositary's corporate trust office or by providing appropriate instructions to their broker. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to holders or a person the holder designates at the office of the custodian. Or, at holder's request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, to the extent permitted by law.

# Interchange between Certificated ADSs and Uncertificated ADSs

Holders may surrender their certificated American depositary receipts ("ADRs") to the depositary for the purpose of exchanging their certificated ADR for uncertificated ADSs. The depositary will cancel such certificated ADRs and will send holders a statement confirming that they are the owners of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to holders a certificated ADR evidencing those ADSs.

# **Voting Rights**

Holders may instruct the depositary to vote the shares or other deposited securities underlying their ADSs at any meeting at which they are entitled to vote pursuant to any applicable law, the provisions of the Articles of Association, and the provisions of or governing the deposited securities. Voting instructions may be given only in respect of a number of ADSs representing an integral number of shares or other deposited securities. Otherwise, holders could exercise their right to vote directly if they withdraw the shares. However, they may not know about the meeting sufficiently enough in advance to withdraw the shares.

If Genmab asks for holders' instructions and upon timely notice from Genmab by regular, ordinary mail delivery, or by electronic transmission, as described in the Deposit Agreement, the depositary will notify holders of the upcoming meeting at which such holders are entitled to vote pursuant to any applicable law, the provisions of Genmab's Articles of Association, and the provisions of or governing the deposited securities, and arrange to deliver Genmab's voting materials to such holders. The materials will include or reproduce (a) such notice of meeting or solicitation of consents or proxies; (b) a statement that the ADS holders at the close of business on the ADS record date will be entitled, subject to any applicable law, the provisions of the Articles of Association, and the provisions of or governing the deposited securities, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the shares or other deposited securities represented by such holder's ADSs; and (c) a brief statement as to the manner in which such instructions may be given to the depositary. Voting instructions may be given only in respect of a number of ADSs representing an integral number of shares or other deposited securities. For instructions to be valid, the depositary must receive them in writing on or before the date specified. The depositary will try, as far as practical, subject to applicable law and the provisions of the Articles of Association, to vote or to have its agents vote the shares or other deposited securities (in person or by proxy) as holders instruct. The depositary will only vote or attempt to vote as holders instruct.

A precondition for exercising any such voting rights is that the ADS holder providing voting instructions on the ADS record date remains a holder with respect to such ADSs on the record date fixed by the Company under Danish law for such meeting. By providing voting instructions to the depositary, the ADS holder is deemed to agree that it will remain as a holder of the ADSs for which it is providing voting instructions until at least the Danish record date or such other date required under applicable Danish law, and the depositary shall only be obligated to confirm the ownership of ADS holders as of the ADS record date.

Genmab cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote the shares underlying their ADSs. In addition, there can be no assurance that ADS holders and beneficial owners generally, or any holder or beneficial owner in particular, will be given the opportunity to vote or cause the depositary or the custodian, as applicable, to vote on the same terms and conditions as Genmab's shareholders.

The depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that holders may not be able to exercise their right to vote and they may have no recourse if the shares underlying their ADSs are not voted as they requested.

In order to give holders a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if Genmab requests the depositary to act, it will give the depositary notice of any such meeting and details concerning the matters to be voted at least 30 days in advance of the meeting date.

# Reclassifications, Recapitalizations and Mergers

If Genmab:	Then
II Geilliau.	1 11011

Changes the nominal or par value of Genmab's shares

Reclassifies, splits up or consolidates any of the deposited securities

Distributes securities on the shares that are not distributed to holders, or

Recapitalizes, reorganizes, merges, liquidates, sells all or substantially all of Genmab's assets, or takes any similar action The cash, shares or other securities received by the depositary will become deposited securities.

Each ADS will automatically represent its equal share of the new deposited securities.

The depositary may distribute some or all of the cash, shares or other securities it received. It may also deliver new ADSs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

### **Amendment and Termination**

# Amendment

Genmab may agree with the depositary to amend the Deposit Agreement and the form of ADR without their consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, including expenses incurred in connection with

foreign exchange control regulations and other charges specifically payable by ADS holders under the Deposit Agreement, or materially prejudices a substantial existing right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the time an amendment becomes effective, holders are considered, by continuing to hold their ADSs, to agree to the amendment and to be bound by the ADRs and the Deposit Agreement as amended. If any new laws are adopted which would require the Deposit Agreement to be amended in order to comply therewith, Genmab and the depositary may amend the Deposit Agreement in accordance with such laws and such amendment may become effective before notice thereof is given to ADS holders.

### **Termination**

The depositary will terminate the Deposit Agreement if Genmab asks it to do so, in which case the depositary will give notice to holders at least 90 days prior to termination. The depositary may also terminate the Deposit Agreement if the depositary has told Genmab that it would like to resign, or if Genmab has removed the depositary, and in either case Genmab has not appointed a new depositary within 90 days. In either such case, the depositary must notify holders at least 30 days before termination.

After termination, the depositary and its agents will do the following under the Deposit Agreement but nothing else: collect distributions on the deposited securities, sell rights and other property and deliver shares and other deposited securities upon cancellation of ADSs after payment of any fees, charges, taxes or other governmental charges. Six months or more after the date of termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the Deposit Agreement, for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest. After such sale, the depositary's only obligations will be to account for the money and other cash. After termination, Genmab shall be discharged from all obligations under the Deposit Agreement except for Genmab's obligations to the depositary thereunder.

# **Books of Depositary**

The depositary will maintain ADS holder records at its depositary office. Holders may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the Company, the ADRs and the Deposit Agreement.

The depositary will maintain facilities in the Borough of Manhattan, The City of New York to record and process the issuance, cancellation, combination, split-up and transfer of ADRs.

These facilities may be closed at any time or from time to time when such action is deemed necessary or advisable by the depositary in connection with the performance of its duties under the Deposit Agreement or at Genmab's reasonable written request.

# **Limitations on Obligations and Liability**

# Limits on Genmab's Obligations and the Obligations of the Depositary and the Custodian; Limits on Liability to Holders of ADSs

The Deposit Agreement expressly limits Genmab's obligations and the obligations of the depositary and the custodian. It also limits Genmab's liability and the liability of the depositary. The depositary and the custodian:

- are only obligated to take the actions specifically set forth in the Deposit Agreement without gross negligence or willful misconduct;
- are not liable if any of Genmab or Genmab's respective controlling persons or agents are prevented or forbidden from, or
  subjected to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing
  required by the terms of the Deposit Agreement and any ADR, by reason of any provision of any present or future law or
  regulation of the United States or any state thereof, the Kingdom of Denmark or any other country, or of any other
  governmental authority or regulatory authority or stock exchange, or on account of the possible criminal or civil penalties
  or restraint, or by reason of any provision, present or future, of the Articles of Association or any provision of or governing
  any deposited securities, or by reason of any act of God or war or other circumstances beyond its control (including,
  without limitation, nationalization, expropriation, currency restrictions, work stoppage, strikes, civil unrest, revolutions,
  rebellions, explosions and computer failure);
- are not liable by reason of any exercise of, or failure to exercise, any discretion provided for in the Deposit Agreement or in the Articles of Association or provisions of or governing deposited securities;

- are not liable for any action or inaction of the depositary, the custodian or Genmab or their or Genmab's respective controlling persons or agents in reliance upon the advice of or information from legal counsel, any person presenting shares for deposit or any other person believed by it in good faith to be competent to give such advice or information;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the Deposit Agreement;
- are not liable for any special, consequential, indirect or punitive damages for any breach of the terms of the Deposit Agreement, or otherwise;
- may rely upon any documents Genmab believes in good faith to be genuine and to have been signed or presented by the proper party;
- disclaim any liability for any action or inaction or inaction of any of Genmab or Genmab's respective controlling persons or agents in reliance upon the advice of or information from legal counsel, accountants, any person presenting shares for deposit, holders and beneficial owners (or authorized representatives) of ADSs, or any person believed in good faith to be competent to give such advice or information; and
- disclaim any liability for inability of any holder to benefit from any distribution, offering, right or other benefit made available to holders of deposited securities but not made available to holders of ADS.

The depositary and any of its agents also disclaim any liability (i) for any failure to carry out any instructions to vote, the manner in which any vote is cast or the effect of any vote or failure to determine that any distribution or action may be lawful or reasonably practicable or for allowing any rights to lapse in accordance with the provisions of the Deposit Agreement, (ii) the failure or timeliness of any notice from Genmab, the content of any information submitted to it by Genmab for distribution to holders or for any inaccuracy of any translation thereof, (iii) any investment risk associated with the acquisition of an interest in the deposited securities, the validity or worth of the deposited securities, the credit-worthiness of any third party, (iv) for any tax consequences that may result from ownership of ADSs, shares or deposited securities, or (v) for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary, provided that in connection with the issue out of which such potential liability arises the depositary performed its obligations without gross negligence or willful misconduct while it acted as depositary.

In the Deposit Agreement, Genmab agrees to indemnify the depositary under certain circumstances.

#### **Requirements for Depositary Actions**

Before the depositary will issue, deliver or register a transfer of an ADS, split-up, subdivide or combine ADSs, make a distribution on an ADS, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third
  parties for the transfer of any shares or other deposited securities and payment of the applicable fees, expenses and charges
  of the depositary;
- satisfactory proof of the identity and genuineness of any signature or any other matters contemplated in the Deposit Agreement; and
- compliance with (A) any laws or governmental regulations relating to the execution and delivery of ADRs or ADSs or to
  the withdrawal or delivery of deposited securities and (B) such reasonable regulations and procedures as the depositary may
  establish, from time to time, consistent with the Deposit Agreement and applicable laws, including presentation of transfer
  documents.

The depositary may refuse to issue and deliver ADSs or register transfers of ADSs generally when the register of the depositary or Genmab's transfer books are closed or at any time if the depositary or Genmab determines that it is necessary or advisable to do so.

### Holders' Right to Receive the Shares Underlying Their ADSs

Holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (1) the depositary has closed its transfer books or Genmab has closed its transfer books; (2) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (3) Genmab is paying a dividend on its shares;
- when holders owe money to pay fees, taxes and similar charges;
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities, or
- other circumstances specifically contemplated by Section I.A.(l) of the General Instructions to Form F-6 (as such General Instructions may be amended from time to time); or
- for any other reason if the depositary or Genmab determines, in good faith, that it is necessary or advisable to prohibit withdrawals.

The depositary shall not knowingly accept for deposit under the Deposit Agreement any shares or other deposited securities required to be registered under the provisions of the Securities Act, unless a registration statement is in effect as to such shares.

This right of withdrawal may not be limited by any other provision of the Deposit Agreement.

**Execution Version CONFIDENTIAL** 

[\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

## JOINT COMMERCIALIZATION AGREEMENT

by and between

**GENMAB A/S** 

and

**SEAGEN INC.** 

Dated as of October 19, 2020

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## **SCHEDULES**

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

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#### OINT COMMERCIALIZATION AGREEMENT

THIS JOINT COMMERCIALIZATION AGREEMENT (this "<u>Agreement</u>") is made as of October 19, 2020 (the "<u>Effective Date</u>"), by and between GENMAB A/S, a Danish corporation ("<u>Genmab</u>"), and SEAGEN INC. (f/k/a SEATTLE GENETICS, INC.), a Delaware corporation ("<u>SGI</u>"). Genmab and SGI are sometimes referred to herein, individually, as a "<u>Party</u>" and, collectively, as the "<u>Parties</u>."

#### RECITALS

**WHEREAS**, Genmab and SGI entered into a License and Collaboration Agreement, dated as of October 7, 2011 (as amended from time to time, the "<u>Collaboration Agreement</u>"), to, among other things, collaborate on the development and commercialization of Collaboration Products (as defined in the Collaboration Agreement);

**WHEREAS**, the Parties and their Affiliates are jointly developing the Product (as defined below) as a Collaboration Product pursuant to the Collaboration Agreement; and

**WHEREAS**, upon obtaining Regulatory Approval in relevant jurisdictions, the Parties have agreed to Commercialize the Product, and have allocated to each Party the right to lead Commercialization in certain Major Markets (as defined below) and other territories, with Genmab having certain rights to co-Promote (as defined below) the Product in the United States, in each case, on the terms and subject to the conditions contained in this Agreement, which terms and conditions amend and further define the terms of the Collaboration Agreement.

**NOW**, **THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

#### **ARTICLE 1 DEFINITIONS**

As used in this Agreement, the following terms shall have the following meanings:

- **1.1** "Adverse Event" means any unfavorable and unintended medical occurrence in a human patient or subject who is administered the Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of the Product, whether or not considered related to the Product.
- **1.2** "<u>Affiliate</u>" of a Person means any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Person. As used in this definition of Affiliate, the term "control" means the direct or indirect ownership of fifty percent (50%) or more of the stock having the right to vote for directors thereof or the ability to otherwise control the management thereof.
- **1.3** "<u>Allowable Expenses</u>" means, with respect to the Product for any period (or until expiration of the applicable Royalty Term as specified below), subject to the provisions of this

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Agreement, the following expenses that are incurred by a Party or any of its Affiliates and are directly attributable or reasonably allocable to Commercialization activities, Medical Affairs Activities, or other relevant activities indicated below for the Product during such period with respect to the Major Markets (or, with respect to the Territory for Sections [\*], and as otherwise indicated below), in each case, determined in accordance with the Collaboration Accounting Standards:

- 1.3.1 [\*];
- 1.3.2 [\*];
- 1.3.3 [\*];

**1.3.4** to the extent that the Parties have agreed to Manufacturing of the Product internally by a Party, itself or through an Affiliate, in each case, pursuant to <u>Section 6.3</u> or <u>Section 6.4</u> (as applicable), [\*]; *provided*, that such [\*] has been approved by the JFT and is included in the Global Manufacturing Plan; *provided*, *further*, that the [\*];

- 1.3.5 [\*];
- 1.3.6 [\*];
- **1.3.7** [\*];
- 1.3.8 [\*];
- 1.3.9 [\*];
- 1.3.10 [\*];
- 1.3.11 [\*];
- 1.3.12 [\*]; and
- 1.3.13 [\*];

provided, that, in each of Sections [\*], such expenses shall be included within Allowable Expenses for the Product only to the extent consistent with the budget included in the applicable Approved Plan (as adjusted pursuant to this Agreement). The components of Allowable Expenses shall be calculated in accordance with the applicable definition thereof and the applicable terms of this Agreement, including the Collaboration Accounting Standards, and shall be determined and charged as provided in Section 5.1. If any cost or expense is directly attributable or reasonably allocable to more than one activity, such cost or expense shall only be counted as an Allowable Expense with respect to one of such activities. Where appropriate, the Parties, through the JFT, may agree that certain Allowable Expenses shall be determined and charged on the basis of a specified annual charge or as a percentage of Net Sales. For clarity, Allowable Expenses shall exclude (i) any expenses that are deductible in the definition of Net Sales, (ii) any Indirect Taxes

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that are reasonably recoverable from a Governmental Authority, (iii) any expenses treated as Development Costs under this Agreement or "Joint Development Costs" (as defined in the Collaboration Agreement) thereunder, and (iv) any Commercial Packaging and Labeling Costs and Manufacturing Costs for Product for the Royalty Territory.

- 1.4 "Applicable Law" means any law or statute, any rule or regulation issued by a Governmental Authority (including courts and Regulatory Authorities), as well as and any judicial, governmental, or administrative order, judgment, decree or ruling, in each case, as applicable to the subject matter and the Parties at issue (including the marketing, sale, and promotion of pharmaceutical products for human use), including GxP and any other rules, regulations, guidelines, or other requirements of Regulatory Authorities. For example, (a) in the United States, Applicable Law includes the FFDCA, the Public Health Service Act, the Prescription Drug Marketing Act, the Federal False Claims Act (31 U.S.C. §3729 et seq.), the Federal Health Care Program Anti-Kickback Law (42 U.S.C. §§1320a-7b), and all rules and regulations promulgated under any the foregoing, (b) in the EU, Applicable Law includes the Directive 2001/83/EC on the Community code relating to medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products, the related national implementing laws and regulations of individual EU member states, provisions of the national laws and industry and professionals codes in individual EU member states governing anti-bribery and anti-kickback practices, and (c) Applicable Law includes foreign equivalents of the foregoing. In addition, Applicable Law includes any law, rule, regulation, ordinance, directive, interpretation, judgment, or decision of any Governmental Authority in relation to data protection; privacy; restrictions on, or requirements in respect of, the processing of personal data of any kind, including the Regulation (EU) 2016/679 and the Health Insurance Portability and Accountability Act of 1996 (collectively, "Data Protection Laws").
- 1.5 "Approved Plans" means the Global Development Plan (including the Global Regulatory Plan incorporated therein), the Commercialization Plans, the Medical Affairs Plans, and the Global Manufacturing Plan, in each case, as amended from time to time, and as approved in accordance with the terms hereof, including any corresponding budgets incorporated therein, as the context requires. For clarity, references herein to the "applicable Approved Plan(s)" shall be deemed to be followed by the phrase "(if any)," and such references shall not limit the activities of SGI in the Royalty Territory if such activities are not subject to an Approved Plan.
- **1.6** "<u>Approved Subcontractors</u>" means any Third Party subcontractor (including for clarity any CSO) engaged by a Party or its Affiliate to perform activities under this Agreement that is either (i) set forth on **Schedule 1.6** or (ii) approved by a Committee to perform specific obligations of the subcontracting Party under this Agreement (including under the Global Development Plan).
- 1.7 "Biosimilar Product" means, (a) in respect of the Product as sold in the United States, a biological product approved under the Public Health Service Act 351(k) that is highly similar to the Product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between such product and the Product in terms of safety, purity and potency; (B) in respect of the Product as sold in the EU, a biological product approved under Article 10(4) of Directive 2001/83/EC and Section 4, Part II, Annex I to such Directive based on the demonstration of the similar nature of such biological medicinal

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product and the Product; and (C) in respect of the Product as sold outside the United States and outside of the EU, a biological product approved under a similar regulatory pathway as in the United States or in the EU, if such pathway exists in such territory.

- **1.8** "BLA" means a Biologics License Application submitted to FDA, and all supplements and amendments that may be submitted with respect to the foregoing.
- **1.9** "Business Day" means a day that is not a Saturday, Sunday or a day on which banking institutions in New York, New York or Copenhagen, Denmark are required by Applicable Law to remain closed.
- **1.10** "Centralized Procedure" means, to the extent compulsory or permitted for the Regulatory Approval of a pharmaceutical product in Iceland, Liechtenstein, Norway, or any country in the EU, the procedure administrated by the EMA which results in a single Regulatory Approval granted by the European Commission (excluding any pricing or reimbursement approval) that is valid in all countries in the EU and, following recognition, in Iceland, Liechtenstein and Norway.

### 1.11 [\*].

- **1.12** "China" means, for purposes of this Agreement, the People's Republic of China, including the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and the Taiwan Region.
- **1.13** "<u>Clinical Supply</u>" means, with respect to the Product, Product intended or used for the purpose of Development or obtaining Regulatory Approval of the Product in accordance with the Global Development Plan.
- **1.14** "<u>Clinical Supply Agreement</u>" means the Tisotumab Vedotin Clinical Supply Agreement, by and between Genmab and SGI, dated as of March 15, 2018, as amended.
- **1.15** "<u>Clinical Trial</u>" means a Phase I Clinical Trial, a Phase II Clinical Trial, a Phase III Clinical Trial, a Phase III-B Study, or a Phase IV Study, as the case may be, as such terms are defined in the Collaboration Agreement. For clarity, "<u>Clinical Trials</u>" do not include any investigator-initiated trials or investigator-sponsored research, which shall be considered Medical Affairs Activities.
- **1.16** "CMC Development" means the Development activities related to the composition, manufacture, and specification of the drug substance and the drug product (including Combination Products in a single formulation) intended to assure the proper identification, quality, purity and strength of the drug, including site transfer (as conducted pursuant to and in accordance with this Agreement), test method development and stability testing, process development, process improvements (*i.e.*, improving product robustness or manufacturing efficiencies), drug substance development, process validation, process scale-up, formulation development, delivery system development, QA and QC development.
- **1.17** "CMC Development Costs" means, with respect to the Product, the [\*] and [\*] that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly

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attributable or reasonably allocable to CMC Development activities undertaken directly or indirectly by such Party or any of its Affiliates with respect to the Product anywhere in the Territory, in each case, determined in accordance with the Collaboration Accounting Standards; *provided*, that the costs incurred by a Party or any of its Affiliates directly attributable or reasonably allocable to the establishment (but not the ongoing supply costs) of site(s) for the Manufacture of Product shall [\*].

- **1.18** "Collaboration" means the collaboration between Genmab and SGI and their respective Affiliates for the Development, Manufacturing, and Commercialization of the Product pursuant to this Agreement and the Collaboration Agreement.
- **1.19** "Collaboration Accounting Standards" means (a) in the case of SGI, U.S. generally accepted accounting principles (GAAP), and (b) in the case of Genmab, International Financial Reporting Standards (IFRS), in each case ((a) and (b)), as consistently applied by such Party and its Affiliates.
- **1.20** "Combination Product" means, solely with respect to Net Sales of a Product in or reasonably allocable to the Royalty Territory, any product or therapy containing (a) as a single formulation, (i) the Product and (ii) one or more other active pharmaceutical ingredients (that are not the Product) (the "Other Components"), or (b) in a single package or container or intended and approved for marketing as a coordinated use, where the Product and the Other Component(s) are both sold by the relevant Selling Party, two or more products or therapies as components including
- (i) the Product, and (ii) one or more Other Components.
- **1.21** "Combined Major Market Plans" means the Combined Major Market Commercialization Plan, and the Combined Major Market Medical Affairs Plan, individually or collectively, as the context requires.
- **1.22** "Commercial Packaging and Labeling Costs" means the [\*] and [\*] incurred by a Party or its Affiliates that are directly attributable or reasonably allocable to Packaging and Labeling of Commercial Supply (including safety stock) conducted by or on behalf of a Party or its Affiliates and calculated in accordance with the Collaboration Accounting Standards.
- **1.23** "Commercial Supply" means, with respect to the Product, Product intended or used for the purpose of Commercializing (including Launching and maintaining safety stock) the Product in accordance with the Commercialization Plans (for clarity, whether such Product was Manufactured prior to, on, or after the date on which Regulatory Approval was obtained for the Product). For clarity, Clinical Supply shall not constitute Commercial Supply.
- **1.24** "Commercialization" means, with respect to the Product, any and all activities to establish and maintain commercial sales for the Product which are undertaken pursuant to an Approved Plan or by SGI with respect to the Royalty Territory. These activities shall include: (a) the pre-Launch marketing and other Launch and Launch preparation activities for the Product, including conducting training of Sales Representatives and any other personnel conducting Commercialization activities, (b) the marketing, Promotion, offering for sale and selling of the Product, (c) importing and exporting the Product for commercial sale, (d) Manufacturing the Product for commercial sale (except for CMC Development activities and Manufacturing

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performed prior to the First Regulatory Approval, including inventory build to support the first Launch, each of which shall be considered Development activities), (e) Sales and Distribution activities, (f) market access and health economics and outcomes research ("<u>HEOR</u>") activities, and (g) Hospital and Organized Customer Activities, in each case ((a) through (g)), in accordance with the applicable Approved Plan. For the avoidance of doubt, as used herein, "<u>Commercialization</u>" shall not include Manufacture of the Product other than Manufacturing for commercial sale following the First Regulatory Approval. When used as a verb, "<u>Commercialize</u>" means to engage in Commercialization.

- **1.25** "Commercialization Costs" means those [\*] and [\*] incurred by a Party or its Affiliates for Commercialization activities conducted by or on behalf of such Party or its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to Commercialization activities for the Product for the Major Markets, in each case, determined in accordance with the Collaboration Accounting Standards, but only to the extent consistent with the applicable Commercialization Plan and the budget included for such activities; *provided*, that where appropriate, the Parties, through the JCC, may agree that [\*]. Notwithstanding the foregoing, Commercialization Costs do not include (i) [\*], (ii) [\*], or (iii) [\*]. For clarity, Commercialization Costs shall exclude [\*].
- **1.26** "Commercialization Plan" means the Combined Major Market Commercialization Plan, the SGI Major Market Commercialization Plan, and the Genmab Major Market Commercialization Plan, or any one or more of them, as the context requires.
- 1.27 "Commercially Reasonable Efforts" means (a) with respect to the efforts to be [\*] by a Party to [\*] other than with respect to [\*], the [\*] and [\*] that such Party and its Affiliates would [\*] to [\*] a [\*] under [\*], and (b) with respect to the [\*] of the Product under this Agreement, the level of efforts and [\*] substantially [\*] to those efforts and [\*] by a Party and its Affiliates for [\*] of [\*] and at a [\*] in its [\*], taking into account commercially relevant factors such as [\*]. Commercially Reasonable Efforts shall be determined on a [\*] and [\*] basis for the Product and it is anticipated that the [\*] of [\*] may be [\*] for [\*], and may [\*], reflecting [\*] in the [\*] of the Product and the market(s) and indication(s) involved. In addition, the Parties recognize that (i) one or more market(s) or indication(s) may not represent a commercially reasonable opportunity, and therefore may not merit the allocation of any [\*], and (ii) the use of Commercially Reasonable Efforts may result in ceasing Commercialization of the Product for one or more market(s) or indication(s). Further, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder or under the Collaboration Agreement, the impact of such performance failure will [\*].
- **1.28** "Committee" means any of the Joint Steering Committee, the Joint Development Committee, the Joint Commercialization Committee, the Joint Medical Affairs Team, the Joint Chemistry, Manufacturing & Controls Team, or the Joint Finance Team, individually or collectively, as the context requires.
- **1.29** "Control" and "Controlled by" mean, with respect to any information or intellectual property right, possession by a Party or any of its Affiliates of the ability to grant the right to access or use, or to grant a license or a sublicense to, such information or intellectual property right as provided for herein or in the Collaboration Agreement without violating the terms of any agreement

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or other arrangement with any Third Party.

- **1.30** "Core Data Sheet" means a document setting forth material information relating to safety, efficacy, indications, dosing, pharmacology and other information concerning the Product that will serve as a global reference document and, subject to Section 8.1.6(a), the basis for local labeling for use in regulatory filings and discussions with Regulatory Authorities in the Territory.
- **1.31** "Corporate Names" means (a) in the case of SGI, the trademarks "Seagen" and "Seattle Genetics" and the SGI corporate logo or such other names and logos as SGI may designate in writing from time to time and (b) in the case of Genmab, the trademark "Genmab" and the Genmab corporate logos or such other names and logos as Genmab may designate in writing from time to time, in each case ((a) and (b)), together with any variations and derivatives thereof.
  - **1.32** "CSO" means a contract sales force organization.
- **1.33** "CVO Activities" means, with respect to the Product: (a) meetings with or presentations to (inperson or otherwise) physicians, administrators, or other professionals identified in an applicable Medical Affairs Plan that are conducted in a hospital setting or with Payors, in each case, with respect to clinical value and outcomes (CVO), and (b) clinical value and outcomes activities conducted with any hospital, health system, Payor, or any other Person.
- "Detail" means a face-to-face meeting (including a virtual face-to-face meeting or group presentation, if in accordance with an applicable Approved Plan or otherwise approved by the JCC), including any such meeting conducted in a hospital or physician's office (a) with one or more physicians and other persons included in other medical professional categories identified in the applicable Commercialization Plan (such individuals, "Target Prescribers") (where, in the case of group presentations, each such physician or other person participating in a group presentation shall be counted as a separate Detail), in each case, who are permitted under the Applicable Law of the country in which they work to prescribe the applicable Product, in which such meeting key Product attributes are orally presented consistent with the terms of this Agreement. As of the Effective Date and so long as the Product has obtained Regulatory Approval for only one Disease in the United States (or other country or region in a Major Market), "Details" for purposes of this Agreement include only Primary Position Details; provided, that in connection with the Launch of the Product for a second or subsequent Disease in the United States (or other country or region in a Major Market), the Parties may determine to include Secondary Position Details as "Details" hereunder, in which case the Parties shall also review and determine the terms and conditions applicable to Primary Position Details and Secondary Position Details under this Agreement. For the avoidance of doubt, (i) a mere Sample drop without discussion with the professional about the Product shall not be considered a Detail, and (ii) any contact between a Sales Representative and a Payor (as distinguished from calls on individual HCPs who may be affiliated with a Payor in connection with their professional prescribing decisions) shall not be considered a Detail. "Detail," when used as a verb, and "Detailing" shall have correlative meanings.
- **1.35** "<u>Development</u>" means all research, non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, statistical analysis, delivery system development, the performance of Clinical Trials (including the Manufacturing of Product for use in Clinical Trials) and other activities, in

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each case, which are reasonably necessary to prepare submissions for, and obtain or maintain, Regulatory Approval of the Product, including lifecycle management studies and other activities. For the avoidance of doubt, as used herein "Development" shall include CMC Development and Manufacturing of the Product prior to the First Regulatory Approval.

- Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to Development activities undertaken directly or indirectly by or on behalf of such Party or any of its Affiliates with respect to the Product pursuant to the Global Development Plan anywhere in the Territory, (b) [\*] and [\*] incurred by a Party or any of its Affiliates with respect to [\*] of the Product Manufactured prior to the First Regulatory Approval, and (c) [\*], in each case ((a) through (c)), determined in accordance with the Collaboration Accounting Standards and as set forth in an applicable Approved Plan. For clarity, "Development Costs" shall include: (i) [\*]; (ii) [\*] and [\*] incurred in connection with the planning and conduct of any Clinical Trials, including [\*] therefor; (iii) [\*] and [\*] for research, non-clinical or clinical purposes prior to the First Regulatory Approval, and (iv) [\*] in connection with Manufacturing for Clinical Supply, in each case ((i)-(iv)), determined in accordance with the Collaboration Accounting Standards and set forth in an applicable Approved Plan. Development Costs shall exclude [\*] and [\*] incurred in connection with the planning and conduct of investigator-initiated trials or investigator-sponsored research, which shall be considered [\*].
- **1.37** "<u>Disease</u>" means a disease condition for which the Product has received Regulatory Approval to treat having a distinct histology (*e.g.*, carcinoma) or affected organ (*e.g.*, lung).
  - **1.38** "Dollars" or "\$" means the legal tender of the United States.
- **1.39** "<u>Drug Regulatory Approval Application</u>" or "<u>DAA</u>" means an application for Regulatory Approval required before commercial sale or use of the Product in a regulatory jurisdiction, including a BLA filed with the FDA, an MAA filed with EMA in the EU or the Regulatory Authority of a country in the European Economic Area, or any foreign equivalents thereof.
- **1.40** "<u>EFTA</u>" means the European Free Trade Association, as its membership may be constituted from time to time, and any successor thereto.
  - **1.41** "EMA" means the European Medicines Agency and any successor agency(ies) thereto.
- 1.42 " $\underline{\mathrm{EU}}$ " means the European Union, as its membership may be constituted from time to time, and any successor thereto.
  - **1.43** "EU14" means [\*].
- **1.44** "<u>Europe</u>" means the United Kingdom, each member state of EU and the EFTA as of the Effective Date (whether or not such countries remain member states of the EU or EFTA), and each member state of the EU and the EFTA from time to time, including the countries set forth on **Schedule 1.44**.

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- **1.45** "<u>European Commission</u>" means the executive body of the EU that is responsible for, among other things, granting marketing authorization for medicinal products through the Centralized Procedure.
- **1.46** "FDA" means the United States Food and Drug Administration, and any successor agency(ies) thereto.
- **1.47** "FFDCA" means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.).
- **1.48** "First Regulatory Approval" means the first Regulatory Approval of the Product in any jurisdiction in the Territory.
- 1.49 "FTE" means the equivalent of the work of one (1) employee full time for one (1) Year consisting of a total of (a) [\*] hours per Year for employees of a Party or its Affiliate [\*] and (b) [\*] hours per Year for employees of a Party or its Affiliate [\*] (or, in each case ((a) and (b)), such other number as may be agreed to by the Parties by mutual Party Written Consent, or by the JSC) directly related to the Commercialization of the Product, or any other activities contemplated under this Agreement. Any such employee who devotes less than [\*] hours or [\*] hours, as applicable, per Year (or such other number as may be agreed by the Parties by Party Written Consent or by the JSC) shall be treated as an FTE on a pro-rata basis upon the actual number of hours worked divided by [\*] or [\*] (or such other number as may be agreed by the Parties by mutual Party Written Consent, or by the JSC).
- **1.50** "FTE Costs" means, with respect to FTEs for Development, Manufacturing, Commercialization and other activities conducted under this Agreement for the Product, the cost of an FTE based on a blended global rate of [\*] for all activities conducted under this Agreement for the Product. Commencing January 1, 2021 and upon January 1 of each Year thereafter, such rate will be adjusted in accordance with the [\*].
  - **1.51** "Genmab Major Market" means [\*].
- **1.52** "Global Plan" means the Global Development Plan (including the Global Regulatory Plan incorporated therein) and the Global Manufacturing Plan, individually or collectively, as the context requires.
- **1.53** "Good Clinical Practice" or "GCP" shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of clinical trials, including the U.S. Code of Federal Regulations ("CFR") Title 21, ICH GCP Guidelines E6(R1), current step 4 version, dated 10 June 1996, national legislation implementing European Community Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, European Community Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards to investigational medicinal products for human use, in each case as amended from time to time.

- **1.54** "Good Laboratory Practice" or "GLP" shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including the CFR Title 21, national legislation implementing European Community Directive 2004/9/EC of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) and European Community Directive 2004/10/EC of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, in each case as amended from time to time.
- **1.55** "Good Manufacturing Practice" or "GMP" shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including the CFR Title 21, ICH GMP Guidelines Q7, current step 4 version, dated 10 November 2000, national legislation implementing European Community Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use as amended by European Community Directives 2003/94/EC, the Rules Governing Medicinal Products in the European Community, Volume 4, including annexes, in each case as amended from time to time.
- **1.56** "Governmental Authority" means any supranational, national, federal, state, provincial, country, city or local government or any agency, department, authority, court, or other instrumentality thereof, including any Regulatory Authority.
  - **1.57** "GxP" means GCP, GLP or GMP or any combination thereof, as applicable.
- **1.58** "<u>Healthcare Professional</u>" or "<u>HCP</u>" mean any member of the medical, pharmacy or nursing professions who in the course of his or her professional activities may prescribe, administer or dispense to an enduser a medicinal product.
- 1.59 "Hospital and Organized Customer Activities" means, with respect to field-based efforts regarding the Product: (a) meetings with or presentations to (in-person or otherwise) physicians, administrators, or other professionals identified in an applicable Commercialization Plan, that are conducted in a hospital setting, or within Integrated Delivery Networks (IDNs), group practices, Accountable Care Organizations (ACOs) or other healthcare systems; and (b) activities conducted with respect to formularies with hospitals, health systems, or integrated health care networks; but excluding, in each case, activities involving (i) Payors, pathways, clinical value, outcomes, or other related terms, (ii) the negotiation or, unless otherwise engaged in by SGI's Sales Representatives or MSLs (at SGI's sole discretion) with respect to the Product in the United States, the implementation, in each case, of agreements with hospitals, health systems, or integrated health care networks, or (iii) distribution partners (including wholesalers, specialty distributors and pharmacies).
- **1.60** "ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use of the World Health Organization, or any successor conference, council or organization.

- **1.61** "IND" means (a) an Investigational New Drug Application, or successor application, filed with the FDA or its equivalent in any country outside the United States where a regulatory filing is required or obtained to conduct a clinical trial or (b) with respect to any country where a regulatory filing is not required or obtained to conduct a clinical trial, the first enrollment of a patient in the first trial involving the first use of the Product in humans.
  - **1.62** "Indirect Taxes" means value added taxes, sales taxes, consumption taxes and other similar taxes.
- **1.63** "<u>Information</u>" means all technical, scientific, regulatory and other information, results, knowledge, techniques and data, in whatever form and whether or not confidential, proprietary, patented or patentable, invention disclosures, plans, processes, practices, methods, knowledge, know-how, skill, experience, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data or descriptions. For clarity, Information does not include issued Patents or the inventions claimed thereby.
- **1.64** "Joint Committee Consent" means the mutual consent or agreement of both Parties' representatives on a specified Committee, Team, or Working Group (or, if no other Committee is specified, the JSC) documented in the meeting minutes of such Committee, Team, or Working Group explicitly (*i.e.*, identified as a Joint Committee Consent) and confirmed as accurate by representatives of each Party on the applicable Committee, Team, or Working Group in accordance with Section 2.10.2 or a writing signed by at least one representative of Genmab and one representative of SGI on such Committee, Team, or Working Group; provided, that if a matter may be approved or agreed by Joint Committee Consent of a specified Committee, Team or Working Group, such approval or agreement may be given by Joint Committee Consent of any other Committee, Team, or Working Group to which such Committee, Team, or Working Group directly or indirectly reports, including, in each case, the JSC.
- **1.65** "Joint Steering Committee" or "JSC" means the joint steering committee established pursuant to the terms of the Collaboration Agreement to provide oversight and endorsement of the development, manufacturing and commercialization plans, and associated budgets, for Collaboration Products, and which JSC's role is expanded and modified hereunder with respect to the Development, Manufacturing, Commercialization and other activities to be conducted hereunder for the Product (*provided* that, for clarity, the JSC shall continue to have the roles and responsibilities as set forth under the Collaboration Agreement with respect to Licensed Products (as defined thereunder) that are not the Product).
- **1.66** "Launch" means, with respect to the Product and an applicable country or territory, the first commercial sale of the Product to a Third Party in such country or territory after receipt of Regulatory Approval with respect thereto (and, if the context requires, for a particular Disease for which the Product has obtained Regulatory Approval). For the avoidance of doubt, sales of the Product prior to receipt of Regulatory Approval in a country or territory, such as so-called "treatment IND sales," "named patient sales," "compassionate use sales," and the like, shall not be construed as a Launch.

- **1.67** "[\*] <u>Agreement</u>" means the [\*], as amended by [\*], dated [\*].
- **1.68** "MAA" means a Marketing Authorization Application filed with the EMA pursuant to the Centralized Procedure or, under Applicable Law for Product, with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure.
- **1.69** "Major Markets" means the Genmab Major Market and the SGI Major Markets, individually or collectively, as the context requires. Unless otherwise indicated, references to "Major Markets" mean (a) with respect to SGI, the SGI Major Markets and (b) with respect to Genmab, (i) the Genmab Major Market and (ii) the [\*].
- **1.70** "Manufacture" means all activities related to the manufacture and supply of the Product, including manufacturing supplies for Development or Commercialization, packaging, labeling, in-process and finished Product testing, release of Product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of Product (except for CMC Development), ongoing stability tests, storage, distribution and shipment, import and export, and regulatory activities directly related to any of the foregoing, but not including any Sales and Distribution activities. For clarity, "Manufacturing" has a correlative meaning.
- **1.71** "<u>Manufacturing Costs</u>" means, with respect to the Product and incurred on or after the Effective Date:
- **1.71.1** To the extent that Product is Manufactured by a Third Party CMO, the [\*] incurred by the Parties that are directly attributable or reasonably allocable to such Manufacture; or
- **1.71.2** To the extent that Product is Manufactured by either Party or its Affiliates, the [\*], as calculated in a manner consistent with a costing methodology as agreed by the JFT, including (if applicable) [\*] consistent with such costing methodology agreed by the JFT, but excluding [\*] not reasonably allocated to the Manufacture of Product in accordance with the cost methodology agreed by the JFT;

provided, in each case, that "Manufacturing Costs" shall not include [\*], or the costs of [\*].

1.72 "Manufacturing Losses" means any and all Losses incurred by one or both Parties, or their Affiliates, resulting from any claim, suit, action, or demand to the extent that such Losses are incurred, relate to, or arise out of the Manufacturing of the Product (including any such claim, suit, action, or demand related to or arising out of Product Liability, breach of Product warranty, the inaccuracy of any representation or warranty, failure to comply with Applicable Law or other breach of any provision of this Agreement, the Collaboration Agreement, or any Related Manufacturing Agreement, in each case, with respect to the Manufacturing of Product), including Losses incurred, related to, or arising under a Related Manufacturing Agreement and Losses resulting, directly or indirectly, from the acts or omissions of any Third Party CMO Manufacturing the Product on the Manufacturing Party's behalf, except in all cases to the extent such Losses (a) are incurred, relate to, or arise out of the gross negligence, recklessness or willful misconduct of the Manufacturing Party (or its Affiliate) or (b) are caused by or result directly from a material

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uncured breach by the Manufacturing Party (or its Affiliate) of any relevant Manufacturing agreement entered into by the Manufacturing Party (or its Affiliate) with any Third Party CMO that Manufactures the Product on the Manufacturing Party's behalf if such material breach is acknowledged by the Manufacturing Party in writing, results from a failure by the Manufacturing Party to make any undisputed payment when due (after giving effect to any available cure period) or is finally determined by a court or arbitrator of competent jurisdiction; *provided*, that the foregoing clause (b) shall not apply to any such material breach that is caused by or results directly from an act or omission of a Third Party including any other Third Party CMO that Manufactures the Product on the Manufacturing Party's behalf.

- 1.73 "Medical Affairs Activities" means the following activities of medical affairs personnel (including, in certain cases, Medical Science Liaisons; provided, for clarity, that not all of the following activities are performed by MSLs) related to the Product: (a) providing input and assistance with consultancy meetings, recommending investigators for Clinical Trials and providing input in the design of trials, and delivering non-promotional scientific exchanges and conducting non-promotional activities such as presenting new Clinical Trial and other scientific Information; (b) providing grants to support continuing medical education or symposia for educational needs related to the Product, including with respect to its therapeutic use; (c) development, publication, presentation and dissemination of publications relating to the Product; (d) responding to medical inquiries and providing medical information services in response to inquiries communicated via Sales Representatives or received by letter, phone call or email, in each case, from HCPs; (e) conducting so-called "named patient," "compassionate use," or similar patient assistance or access programs; (f) providing appropriate support for investigator- initiated trials and investigator-sponsored research; and (g) CVO Activities.
- **1.74** "Medical Affairs Costs" means those [\*] and [\*] that are incurred by such Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonable allocable to Medical Affairs Activities conducted by or on behalf of such Party or its Affiliates for the Product in the Major Markets in accordance with the Medical Affairs Plans. For clarity, Medical Affairs Costs shall exclude [\*]. Medical Affairs costs shall exclude the [\*] and [\*] incurred in connection with the planning and conduct of Clinical Trials, which shall be considered [\*].
- **1.75** "<u>Medical Affairs Plan</u>" means the Combined Major Market Medical Affairs Plan, the SGI Major Market Medical Affairs Plan, or the Genmab Major Market Medical Affairs Plan, or any one or more of them, as the context requires.
- **1.76** "Medical Science Liaisons" or "MSLs" mean those health care professionals employed or engaged by a Party or any of their Affiliates with sufficient health care experience (including at least a four-year degree and either (a) clinical, residency or fellowship experience or (b) other highly specialized training relevant to a specific therapeutic area) to engage in in-depth dialogues with physicians or other HCPs regarding medical issues associated with the Product and who are not Sales Representatives or otherwise engaged in direct selling, Promotion, or Hospital and Organized Customer Activities for the Product.
- **1.77** "Net Profit/Net Loss" means, with respect to the Product during any period, [\*] of the Product in [\*] plus [\*] actually received during such period, less the sum of [\*] and [\*] incurred during such period. For clarity, Net Profit/Net Loss shall be determined prior to application of any

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income or other direct taxes, and if such terms are used individually, "<u>Net Profit</u>" shall mean a positive Net Profit/Net Loss, and "<u>Net Loss</u>" shall mean a negative Net Profit/Net Loss.

- **1.78** "Net Sales" means the gross amount invoiced in arm's-length transactions by Related Parties or, solely in the Royalty Territory, Sublicensees, from or on account of the sale of the Product by such Related Party, or only as to the Royalty Territory, a Sublicensee, to a non- Related Party (including sales to any Third Party distributor, wholesaler, or the like), less the sum of the following:
- **1.78.1** credits or allowances, [\*], on account of price adjustments, recalls, claims, damaged goods, and rejections or returns of items previously sold (including Product returned in connection with recalls or withdrawals);
- **1.78.2** import taxes, export taxes, excise taxes, sales taxes, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind), in each case, to the extent (a) [\*] and (b) [\*];
- **1.78.3** insurance, customs charges, freight, shipping and other transportation costs incurred in shipping Product to such non-Related Parties, in each case, to the extent [\*];
- **1.78.4** amounts written off by reason of uncollectible debt, to the extent consistent with the relevant Party's business practices for its other pharmaceutical products, as determined on a country-by-country basis and in accordance with the Collaboration Accounting Standards (*provided*, that any such amounts subsequently collected will be included in Net Sales for the period in which collected);
- **1.78.5** discounts (including trade, quantity and cash discounts) [\*], cash and non- cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any non-Related Party (including to [\*]); and
- **1.78.6** rebates (or their equivalent), administrative fees, chargebacks and retroactive price adjustments and any other similar allowances [\*] to non-Related Parties (including to [\*]) which effectively reduce the selling price or gross sales of the Product.

All of the foregoing deductions from the gross amount invoiced for such sales of the Product shall be determined in accordance with Collaboration Accounting Standards. Product transferred to non-Related Parties in connection with clinical and non-clinical research and trials, Samples, "named patient sales," "compassionate use sales," or any similar program or bona fide arrangement in which a Related Party agrees to forego a normal profit margin shall give rise to Net Sales only to the extent that any Related Party invoices or receives amounts therefor in excess of the cost of goods thereof.

Product shall be considered "sold" in accordance with Collaboration Accounting Standards. Net Sales shall be determined from the books and records of the Related Party.

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It is understood that any accruals for individual items reflected in Net Sales are periodically trued up and adjusted by each Related Party consistent with its customary practices and in accordance with Collaboration Accounting Standards.

Sale or transfer of Product between any of the Related Parties, or solely in the Royalty Territory, between a Related Party and a Sublicensee, shall not result in any Net Sales, and Net Sales shall be calculated based on any subsequent sales or dispositions to a non-Related Party who is not a Sublicensee. To the extent that any Related Party, or solely in the Royalty Territory, a Sublicensee receives consideration other than or in addition to cash in consideration for the sale of the Product to a non-Related Party and such consideration does not constitute Sublicensing Revenue hereunder in the Major Markets, Net Sales shall include the fair market value of such non-cash consideration for such sale of Product. For clarity, sales by a Related Party (or solely in the Royalty Territory, by a Sublicensee) to a Third Party wholesaler or similar distributor, group purchasing organization, pharmacy benefit manager, or retail chain customer shall be considered sales to a non-Related Party and Net Sales hereunder.

Solely with respect to Net Sales occurring in the Royalty Territory, Net Sales of any Combination Product for the purpose of calculating royalties due under this Agreement shall be determined on a country-by-country basis for a given accounting period as follows: first, the Related Party (or Sublicensee, solely with respect to the Royalty Territory) that owns or otherwise controls the Combination Product shall determine the actual Net Sales of such Combination Product (using the above provisions), and then: such Net Sales amount for the Combination Product shall be multiplied by the fraction A/(A+B), where "A" is the net selling price in such country of the Product, if sold separately for the same dosage as contained in the Combination Product, and "B" is the net selling price in such country of the Other Components in the combination if sold separately for the same dosage as contained in the Combination Product. All net selling prices of the elements of such end-user product or service shall be calculated as the average net selling price of said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any country, no separate sale of either the Product or Other Components included in such Combination Product are made during the accounting period in which the sale was made or if the net selling price for an active ingredient cannot be determined for an accounting period, Net Sales allocable to the Product in each such country shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, on a country-by-country basis, all relevant factors (including variations in potency, the relative contribution and value to the end user of the Product and the Other Components in the combination).

In the case where a drug delivery device is sold with or for use with the Product and included in the gross sales amount, any appropriate adjustment to Net Sales shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account all relevant factors.

**1.79** "Out of Pocket Costs" means amounts paid by a Party to Third Parties for goods

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and services required for such Party to perform its obligations under this Agreement in accordance with any applicable Approved Plan.

- **1.80** "<u>Packaging and Labeling</u>" means secondary packaging, labeling, and serializing (as required by Applicable Law) for the Product.
- **1.81** "Party Combination Study" means any Clinical Trial regarding the combination (including coadministration or other coordinated use) of (a) the Product, on the one hand, and (b) one or more other products developed and/or commercialized by or on behalf of a Party or its Affiliates (including products co-developed by a Party or its Affiliate and a Third Party). A Party Combination Study involving a product developed and/or commercialized by or on behalf of (i) SGI (including products co-developed by SGI or its Affiliate and a Third Party) is referred to herein as an "SGI Party Combination Study" and (ii) Genmab (including products co-developed by Genmab or its Affiliate and a Third Party) is referred to herein as a "Genmab Party Combination Study."
- **1.82** "Party Major Market Commercialization Plan" means the Genmab Major Market Commercialization Plan and the SGI Major Market Commercialization Plan, individually or collectively, as the context requires.
- **1.83** "<u>Party Major Market(s)</u>" means (a) with respect to Genmab, the Genmab Major Market, and (b) with respect to SGI, the SGI Major Markets, individually or collectively, as the context requires.
- **1.84** "<u>Party Major Market Plans</u>" means the Party Major Market Commercialization Plans and the Party Major Market Medical Affairs Plans, individually or collectively, as the context requires.
- **1.85** "<u>Party Major Market Medical Affairs Plan</u>" means the Genmab Major Market Medical Affairs Plan and the SGI Major Market Medical Affairs Plan, individually or collectively, as the context requires.
- 1.86 "Party Tactical Matters" means, with respect to a Party, such Party's operational or tactical-level actions and decisions with respect to matters and functions allocated or delegated to such Party pursuant to (i) a Combined Major Market Plan, (ii) a Party Major Market Plan, (iii) the US Coordination Plan, or (iv) otherwise pursuant to this Agreement with respect to the Product (including, generally, Commercialization activities, Manufacturing activities, and Medical Affairs Activities with respect to the Product) to the extent that such actions or decisions are consistent with the terms of this Agreement, the scope of such allocation or delegation, Applicable Law, and the Combined Major Market Plans, Party Major Market Plans, and US Coordination Plan, including the tactical and strategic matters described in such plans, in each case, in or for such Party's Party Major Market(s) or, subject to ARTICLE 3 and the US Coordination Plan, the United States with respect to Genmab. For clarity, (1) Party Tactical Matters exclude any responsibilities or determinations that (a) are expressly delegated to a Committee hereunder, or (b) expressly require the consent of the other Party or any Committee (including via Joint Committee Consent or Party Written Consent), and (2) "Party Tactical Matters" of Genmab in or for the United States must be consistent with the US Coordination Plan and ARTICLE 3.

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- **1.87** "Party Written Consent" means (a) with respect to a matter to be agreed by the Parties, the mutual written agreement or consent of the Parties, in each case, executed on behalf of each Party by an appropriate officer or employee of such Party; and (b) with respect to a matter to be consented to or approved by a Party, the written consent or agreement of such Party executed by an appropriate officer or employee of such Party. For the avoidance of doubt, a writing evidencing Party Written Consent may be executed by (i) delivery of electronically scanned copies of original signatures delivered by electronic mail or other means of electronic transmission, or (ii) electronic signature (e.g., DocuSign®), but electronic mail without execution will not evidence Party Written Consent.
- **1.88** "Patent Costs" means the [\*] incurred by a Party or any of its Affiliates on or after the Effective Date in connection with the Patent prosecution, maintenance, and enforcement activities conducted pursuant to Sections 14.2 and 14.3 of the Collaboration Agreement or Section 11.6 of this Agreement with respect to the Product.
- **1.89** "Patents" means: (a) patent applications filed in the Territory; (b) all patents, including supplemental protection certificates, that have issued or in the future issue from any of the foregoing, including utility models, design patents and certificates of invention; and (c) all divisionals, continuations, continuations-in-part, reissues, re-examination certificates, renewals, extensions or additions to any such patents and patent applications (as applicable).
- 1.90 "Payments to Third Parties" means any amounts paid to a Third Party (whether in the form of a royalty, up-front payment, milestone payment or otherwise) by or on behalf of a Party following the Effective Date in consideration for the grant of a license or other rights under a Patent or other intellectual property rights controlled by such Third Party that are [\*] to Develop, Manufacture, or Commercialize the Product under (i) a Third Party License Agreement for one or more Major Markets entered into by a Party in accordance with this Agreement, (ii) the [\*] Agreement dated [\*] between [\*] and [\*], as amended (the "[\*] Agreement"), or (iii) the [\*] Agreement.
- **1.91** "Payors" means, pharmacy benefit managers, managed health care organizations, group purchasing organizations, large employers, government agencies and government health care programs (*e.g.*, the U.S. Department of Veterans Affairs and Medicare in any form), and similar programs or organizations.
- **1.92** "Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association, or other entity.
- 1.93 "Post-Market Surveillance" means a program in place after the receipt of Regulatory Approval to be further defined in a pharmacovigilance agreement entered into pursuant to Section 8.2 that provides for (a) monitoring the safety of a product in the market, including reporting of certain Adverse Events to Regulatory Authorities; (b) monitoring, investigating, reporting, and responding to complaints from the market, whether medical, technical, or otherwise; and (c) evaluating whether additional actions, such as a label amendment, dear doctor letter, or recall, may be necessary.
  - **1.94** "Primary Position Detail" means, with respect to the Product, a Detail (a) in which

key attributes of the Product are orally presented consistent with the terms of this Agreement and (b) where the Product is given primary emphasis (*i.e.*, an emphasis that is more important than the emphasis given to any other product presented, as a first position detail).

- **1.95** "Product" means Tisotumab Vedotin, as referenced in the Opt-In Notice dated [\*] provided by SGI to Genmab pursuant to the Collaboration Agreement, in [\*].
- **1.96** "Product Liability" means any liability in respect of any personal injury or death (or risk of personal injury or death) arising from, relating to or otherwise in respect of the use or ingestion of, or exposure to, the Product, whether based on negligence, strict product liability or any other product liability theory, including liability predicated on any alleged or actual manufacturing, design or formulation defect or failure to warn or any breach of any express or implied warranties.
- **1.97** "Product Liability Losses" means any and all Losses that relate to Claims in respect of Product Liability or alleged Product Liability, in each case, anywhere in the Territory.
- 1.98 "Promote" means, with respect to the Product, promotional activities to be conducted by Sales Representatives of a Party in the Major Markets that are set forth in an applicable Commercialization Plan or otherwise approved by the JCC, including the following (as approved by the JCC or set forth in an applicable Commercialization Plan): (a) Detailing; (b) utilizing Promotional Materials during Details; (c) conducting display booths, displaying Promotional Materials and conducting meetings with Target Prescribers in exhibits at conferences and trade shows; (d) sponsoring advertising in journals and publications directed to Target Prescribers; (e) conducting company-directed peer-to-peer programs regarding the Product (including speakers bureau and speaker training) directed at Target Prescribers; and (f) distributing Promotional Materials to Target Prescribers using direct mail, electronic media, digital channels or other appropriate dissemination methods. clarity, "Promotion" shall not include: (i) discussing or responding to questions regarding the Product outside of the approved Product labeling; (ii) independently maintaining a website, call center or medical information hotline for the Product; (iii) taking Product orders or otherwise selling or offering the Product for sale; (iv) Hospital and Organized Customer Activities; or (v) other marketing activities not allocated to the applicable Party under this Agreement or in an approved Commercialization Plan. "Promotion" and "Promotional" shall have the correlative meanings.
- **1.99** "<u>Promotional Materials</u>" means any advertising, marketing, or Promotional materials, any communication, educational or training tools or materials related thereto, and any similar tools or materials (but not including materials for Medical Affairs Activities), in each case, relating to the Product and in any medium.
- 1.100 "QA" means quality assurance activities conducted to ensure that all products are of the quality required for their intended use and that quality systems are maintained in accordance with Applicable Law.
- **1.101** " $\underline{QC}$ " means quality control activities conducted to check or test that specifications are met in accordance with Applicable Law.

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- **1.102** "Quarter" means each of the three (3) month periods ending on March 31, June 30, September 30 and December 31; *provided*, that the first Quarter under this Agreement shall commence on the Effective Date and the final Quarter under this Agreement shall end on the last day of the Term. "Quarterly" shall have the correlative meaning.
- **1.103** "Regulatory Approval" means final regulatory approval (including, where applicable, pricing approval in the event that actual commercial sales are not permitted under Applicable Law absent such approval) required to Commercialize the Product for a disease or condition in accordance with the Applicable Law of a given country or regulatory jurisdiction. In the United States, Regulatory Approval means approval of a New Drug Application, BLA or an equivalent application by the FDA. In the EU, Regulatory Approval means approval of an MAA granted by the European Commission or the Regulatory Authority of a country in the European Economic Area.
- **1.104** "<u>Regulatory Authority</u>" means the FDA, the EMA, the European Commission, the Pharmaceuticals and Medical Devices Agency of Japan, or any comparable national or territorial regulatory entity within the Territory having substantially the same functions.
- **1.105** "Related Manufacturing Agreement" means any supply or quality agreement entered into between the Parties or their respective Affiliates with respect to the Product.
- **1.106** "Related Party" means a Party and its Affiliates. For clarity, Related Party shall not include any distributors, wholesalers or the like unless such entity is an Affiliate of the applicable Party.
- **1.107** "<u>Royalty Territory</u>" means all countries and territories within the Territory except for the Major Markets.
- **1.108** "Sales and Distribution" means all sales and distribution activities for the Product in connection with Commercialization thereof, including customer service, handling of returns, order processing, inventory, warehousing, shipping, serialization compliance, invoicing, booking of sales, distribution and collection of receivables.
- 1.109 "Sales Representative" of a Party means (a) an employee of such Party or an Affiliate of such Party engaged by such Party or Affiliate to Promote the Product on behalf of such Party or such Affiliate, or (b) an Approved Subcontractor, including a CSO, engaged by such Party or Affiliate (to the extent permitted in this Agreement) to Promote the Product on behalf of such Party or such Affiliate, excluding, in each case ((a) and (b)), (i) those employees or independent contractors of either Party or such an Affiliate that are solely engaged in telemarketing, professional education or other indirect activities in support of direct selling, and (ii) Medical Science Liaisons of a Party or such Affiliate. For clarity, "Sales Representatives" do not include employees or Approved Subcontractors engaged in Hospital and Organized Customer Activities.
- **1.110** "Samples" means Product units which are not intended to be sold or traded, which are intended to be distributed to authorized health care professionals, and which are intended to promote the sale of such prescription drug in accordance with 21 U.S.C. §§353(c) and (d), and the

applicable regulations of Title 21 of the U.S. Food and Drug Administration governing prescription drug samples, including 21 C.F.R. Part 203, or any successor provisions to such laws and regulations and in accordance with Applicable Law in any non-U.S. jurisdiction where Product units are to be distributed, including with respect to the EU, Article 96 of Directive 2001/83.

- **1.111** "Secondary Position Detail" means, with respect to the Product, a Detail in which key attributes of the Product are orally presented consistent with the terms of this Agreement, where the Product is given significant but not primary emphasis (*i.e.*, an emphasis that is at least or more important than the emphasis given to any other product presented other than the product that is presented as a Primary Position Detail), as a second position detail.
- **1.112** "Selling Party" means (a) SGI or its Affiliates in the SGI Major Markets and in the Royalty Territory, and (b) Genmab or its Affiliates in the Genmab Major Market.
  - **1.113** "SGI Major Markets" means [\*].
- "Sublicensing Revenue" means (a) all consideration actually received by a Party or its Affiliates 1.114 from a Sublicensee for the grant of a (sub)license to such Sublicensee of rights to Develop and/or Commercialize the Product in one or more countries in a Major Market (a "Major Market Sublicense"), net of any tax or similar withholding obligations imposed by any tax or other Governmental Authority, which consideration may include upfront, milestone, royalty or other payments; provided, that (i) if a Major Market Sublicense also includes rights granted both within the Major Markets and outside of the Major Markets, only the portion of the consideration reasonably allocable to the Major Markets will be included in the calculation of Sublicensing Revenue, (ii) if a Major Market Sublicense also includes rights to any intellectual property not necessary or useful for the Development, Manufacture or Commercialization of the Product, only the portion of the consideration reasonably allocable to the Product will be included in the calculation of Sublicensing Revenue, and (iii) Sublicensing Revenue shall not include any consideration paid by such Sublicensee for bona fide goods or services provided by such Party or its Affiliates to such Sublicensee up to [\*], including a commercially reasonable supply or transfer price for any Product supplied to such Sublicensee, and (b) the amount of [\*]; provided, that if such distributor has been granted rights both within and outside the Major Markets, only the consideration reasonably allocable to the Major Markets will be included in the calculation of Sublicensing Revenue. For clarity, neither (a) nor (b) will include (1) [\*] (provided such consideration does not [\*]), or (2) [\*].
- **1.115** "Supply Chain Management" means the planning, management and execution of internal activities and activities of Third Party suppliers that (a) provide raw materials used in the manufacture of the Product; (b) manufacture, fill and finish, package and label the Product or any component thereof; or (c) test, assist in the release of, hold or distribute the Product or any component thereof. Supply Chain Management also includes management of forecasting activities.
  - **1.116** "<u>Territory</u>" means the entire world.
  - **1.117** "Third Party" means any Person other than Genmab, SGI or an Affiliate of either of them.

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- **1.118** "<u>Third Party License Agreement</u>" means an agreement between a Party and a Third Party pursuant to which a Party in-licenses rights to Patents or other intellectual property rights controlled by such Third Party that are [\*] for the Development, Manufacture or Commercialization of the Product and executed after the Effective Date in accordance with this Agreement, including <u>Section 5.8</u>.
- **1.119** "<u>Trademark Costs</u>" means, subject to <u>Section 11.3</u>, (a) the [\*] (including [\*]) incurred by a Party or any of its Affiliates on or after the Effective Date in connection with (i) the clearance of the Product Trademarks and the establishment of the Product Trademarks in the Major Markets and (ii) the maintenance of rights of the Product Trademarks in the Major Markets and (b) the [\*] and [\*] incurred by a Party or any of its Affiliates on or after the Effective Date in connection with bringing, maintaining and prosecuting any action described in <u>Section 11.3.1</u>, in each case, with respect to the Product and determined in accordance with the Collaboration Accounting Standards.
- **1.120** "<u>United States</u>" or "<u>U.S.</u>" means the United States of America, including its territories and possessions as recognized by the United Nations from time to time, but in all cases including, for clarity, Puerto Rico.
- **1.121** "<u>Year</u>" means a calendar year beginning on January 1 and ending on December 31; *provided*, that the first Year under this Agreement shall commence on the Effective Date and the final Year under this Agreement shall end on the last day of the Term. For clarity, references in this Agreement to "year" without capitalization mean a period of twelve (12) consecutive months (365 or 366 days, as applicable).
- **1.122** Other Definitions; Terms Defined in Collaboration Agreement. Capitalized terms defined elsewhere in this Agreement shall have the meanings ascribed to such terms for all provisions in this Agreement. See the Index of Defined Terms for the location of such other definitions in this Agreement. Except where the context otherwise requires, capitalized terms used in this Agreement without definitions have the meanings ascribed to such terms in the Collaboration Agreement.
- **1.123** Relationship to Collaboration Agreement. In the event a term is defined in this Agreement and in the Collaboration Agreement, the definition in this Agreement shall govern and control with respect to the Product and all matters under this Agreement (but, for clarity, not with respect to other "Licensed Products" as such term is defined in the Collaboration Agreement, subject to <u>ARTICLE 12</u>, which expressly amends and restates the sections of the Collaboration Agreement referenced therein).

### **ARTICLE 2 GOVERNANCE**

## **2.1** Governance Generally.

**2.1.1** <u>General</u>. Each Party shall assign responsibilities for the various operational aspects of the Collaboration allocated to such Party pursuant to this Agreement to those

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portions of its organization that have the appropriate resources, expertise and responsibility for such functions.

2.1.2 <u>Collaboration Committees, Teams and Working Groups</u>. The Parties have established a JSC, a JDT and a joint commercialization team pursuant to the Collaboration Agreement. The Parties desire to establish additional committees or teams or clarify and modify the roles and responsibilities of existing committees or teams formed under the Collaboration Agreement as Committees or Teams hereunder, as provided below, to further oversee the Collaboration, to provide additional decision-making structures, and to provide a forum for discussion of matters relating to the Collaboration, in each case, with respect to the Product. Each Committee established hereunder shall have the responsibilities and authority allocated to it in this <u>ARTICLE 2</u> and elsewhere in this Agreement.

## **2.1.3** <u>Limitations on the Authority of Committees.</u>

- General. No rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree by mutual Party Written Consent. The Parties hereby agree that: (a) no Committee shall have any authority with respect to the amendment, modification or waiver of compliance with any provision of this Agreement, which matters may be approved only by mutual Party Written Consent (and in the case of a waiver of compliance, by Party Written Consent of the Party entitled to waive such compliance); (b) any matter that otherwise would be within the jurisdiction of any Committee may be agreed or resolved by mutual Party Written Consent; (c) any matter that is expressly reserved to the consent or other decision-making authority of one (1) Party in this Agreement may be decided only by such Party; (d) any matter that is expressly reserved to the consent or agreement of both of the Parties may be decided only by mutual Party Written Consent; (e) all determinations made by any Committee shall be subject to and shall comply with the terms of this Agreement; (f) a Committee may not make any decision that is inconsistent with the Combined Major Market Plans unless an amendment to the applicable Combined Major Market Plan addressing such inconsistency is approved by the JSC; and (g) the Committees shall have no authority over Royalty Territory matters except as set forth in Section 2.1.3(b). Additionally, and for the avoidance of doubt, neither the JSC nor the JCC shall have any authority with respect to [\*] in or for the Party Major Market(s) of either Party, or any country therein; provided, that [\*] approved by the JSC. Each Party shall have the exclusive right to [\*] in its Party Major Market(s) [\*], in compliance with Applicable Laws (including antitrust and competition laws).
- **(b)** Additional Royalty Territory Limitations on Committees. Notwithstanding any other provision in this Agreement or the Collaboration Agreement to the contrary, no Committee shall have any decision-making authority with respect to the Development, Manufacturing, or Commercialization of the Product solely in the Royalty Territory or outside the Royalty Territory solely to support Development or Commercialization of the Product in the Royalty Territory ("Royalty Territory Decisions"), and such Royalty Territory Decisions shall be made by SGI at its discretion; *provided*, that such decisions shall be consistent with [\*] (including with respect to [\*]) and applicable terms of this Agreement.

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- **2.2** <u>Joint Steering Committee</u>. The JSC formed under the Collaboration Agreement shall have the following responsibilities with respect to the activities to be conducted for the Product pursuant to this Agreement (*provided* that, for clarity, the JSC shall continue to have the roles and responsibilities as set forth under the Collaboration Agreement with respect to Licensed Products (as defined thereunder) that are not the Product):
- **2.2.1** overseeing the Development, Manufacturing and Commercialization of the Product, generally;
- **2.2.2** approving each Combined Major Market Plan (and budgets therefor, as applicable), including the global Launch plan and Launch sequence set forth in the Combined Major Market Commercialization Plan;
- **2.2.3** subject to <u>Section 8.1.6(a)</u>, approving the Core Data Sheet prepared in accordance with this Agreement, which shall be submitted to it by the JDC, and amendments thereto;
- **2.2.4** approving final target pricing bands for the Product both globally and regionally (with relevant regions recommended by the JCC) in the Territory, in compliance with Applicable Laws (including antitrust and competition laws):
- **2.2.5** approving any Third Party License Agreement for one or more Major Markets in accordance with Section 5.8, approving any amendment or modification to any such Third Party License Agreement, and approving any amendment or modification to any other agreement giving rise to Payments to Third Parties treated as Allowable Expenses or Development Costs hereunder;
- **2.2.6** deciding whether to pursue a Commercial Sublicense for one or more countries in the Major Markets and approving any Commercial Sublicense for a Party Major Market, in each case, in accordance with and to the extent provided in <u>Section 4.7.2</u>;
- **2.2.7** approving any determination to pursue an additional or alternative source of Manufacturing for the Product or any component thereof in accordance with <u>Section 6.3</u> or <u>Section 6.4</u> (as applicable); *provided*, that the specific arrangement(s) for any such Manufacturing, including any Manufacturing by a Party, itself or through an Affiliate, are subject to the review and approval of the JCMCT as provided in <u>Section 6.3</u> or <u>Section 6.4</u> (as applicable);
- **2.2.8** approving any global allocation of Product supply proposed by the JCMCT pursuant to Section 6.7;
- **2.2.9** approving any recommendation from the JDC regarding whether and when to submit a DAA, including a BLA, for the Product anywhere in the Territory;
  - **2.2.10** conducting any other activities as expressly provided for in this Agreement;

and

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**2.2.11** resolving disputes referred to it by other Committees pursuant to this Agreement.

### 2.3 <u>Joint Development Committee.</u>

- Formation and Purpose. Genmab and SGI have established a "Joint Development 2.3.1 Team" or "JDT" pursuant to the Collaboration Agreement and wish to clarify and modify its role by way of forming a "Joint Development Committee" or "JDC" hereunder for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein and to assume the role of the JDT under the Collaboration Agreement solely with respect to the Product (and for clarity the JDT shall continue to have the roles and responsibilities as set forth under the Collaboration Agreement with respect to Licensed Products (defined thereunder) that are not the Product). The JDC shall consist of [\*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and subject to Sections 2.1 and 2.10, the JDC shall be principally responsible for overseeing the Development (other than CMC Development, which shall be subject to the oversight of the JCMCT) of the Product globally under the Collaboration Agreement and this Agreement, including coordination and implementation of activities between the Parties. The JDC shall operate by the procedures set forth in Section 2.10. For clarity, (a) the JDT formed under the Collaboration Agreement shall have no authority or other role with respect to the Product following the Effective Date, and (b) following the Effective Date, references in the Collaboration Agreement to the "Joint Development Team" or "JDT" solely as they relate to the Product shall refer to the JDC under this Agreement.
- Global Development Plan. Prior to the Effective Date, the JDT adopted a Joint 2.3.2 Development Plan and Joint Budget (each, as defined in the Collaboration Agreement) that govern the global Development, Manufacturing, and regulatory activities of the Parties with respect to the Product under the Collaboration Agreement. As promptly as practicable following the Effective Date, the JDC shall (a) update such Joint Development Plan and Joint Budget to the extent necessary to (i) align the contents thereof with this Agreement and the Approved Plans hereunder, including by incorporating the Global Regulatory Plan prepared pursuant to Section 8.1.1 and by revising the Joint Development Plan and Joint Budget to exclude Manufacturing and instead addressing Manufacturing activities in the separate Global Manufacturing Plan to be drafted and approved hereunder, and (ii) otherwise reflect the global Development activities of the Parties with respect to the Product throughout the Territory, and the corresponding budget therefor, and (b) submit such updated plan and budget to the JSC for approval (as approved by the JSC, such plan and budget, collectively, the "Global Development Plan"). Following its approval by the JSC, the Global Development Plan under this Agreement shall replace the Joint Development Plan and Joint Budget under the Collaboration Agreement for all purposes with respect to the Product under this Agreement and the Collaboration Agreement. On an annual basis, or more often as the Parties deem appropriate, the JDC shall prepare amendments to the then-current Global Development Plan for approval by the JSC. The JSC will endeavor to approve the Global Development Plan or such amendments before the end of the then- applicable Year. In the event of any inconsistency between the Global Development Plan and this Agreement, the terms of this Agreement shall prevail. For clarity, and without limiting the treatment of CMC Development Costs as Development Costs, the portions of the existing Joint Development Plan and Joint Budget relating to Manufacturing or CMC Development will not become part of the Global Development Plan pursuant to this Section

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- 2.3.2, and will instead become part of the Global Manufacturing Plan as addressed in Section 6.2.
- **2.3.3** <u>Specific Responsibilities</u>. Subject to the oversight of the JSC, the JDC shall be responsible for overseeing Development strategy for the Product globally under this Agreement. The JDC's responsibilities shall include the following:
- (a) overseeing the preparation of annual updates and other amendments to the Global Development Plan (including the budget therefor) for approval by the JSC;
- **(b)** subject to <u>Section 8.1.6(a)</u>, reviewing and approving a form of Core Data Sheet and submitting a draft thereof to the JSC for its approval pursuant to <u>Section 2.2.3</u>;
- (c) monitoring compliance with the then-current budget included in the Global Development Plan;
- **(d)** reviewing, coordinating and monitoring the activities and progress of the Parties in implementing the Development activities contemplated by the Global Development Plan;
- **(e)** monitoring the activities of its Working Groups, including the JMAT, JRT and CDS Working Group in accordance the terms of this Agreement (*provided*, for clarity, that despite the JDC's global role with respect to Development, its role with respect to the JMAT and Medical Affairs Activities will be limited to the JMAT's responsibilities under this Agreement with respect to the Major Markets);
- **(f)** in consultation with the JRT, recommending to the JSC whether and when to submit a DAA, including a BLA, for the Product anywhere in the Territory;
- **(g)** facilitating the flow of information with respect to the Development of the Product and coordinating such information flow with other Committees, as appropriate;
- **(h)** overseeing the strategic planning and conduct of Clinical Trials consistent with the allocation of sponsorship and responsibility for Clinical Trials set forth in <u>Section 4.6.2</u>; *provided*, that the JDC shall coordinate with the JMAT with respect to the JDC's strategic planning and conduct of Phase III-B Studies and Phase IV Studies;
- **(i)** making forecasts of Clinical Supply requirements for Development of the Product and reviewing the supply of Product;
- **(j)** making recommendations for further Development of the Product, including Development for new indications that are not in the then current Global Development Plan;
  - **(k)** providing Quarterly updates on the JDC's activities to the JSC;
  - **(l)** establishing and implementing a responsibility assignment

matrix consistent with this Agreement to define the roles and responsibilities between the Parties with respect to Development activities; and

**(m)** performing such other functions as the JSC may request from time to time or are expressly assigned to the JDC in this Agreement.

## 2.4 <u>Joint Commercialization Committee</u>.

- **2.4.1** <u>Formation and Purpose</u>. Genmab and SGI have established a joint commercialization team pursuant to the Collaboration Agreement and wish to supersede such joint commercialization team by way of forming a "<u>Joint Commercialization Committee</u>" or "<u>JCC</u>" hereunder for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein. The JCC shall consist of [\*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and subject to <u>Sections 2.1</u> and <u>2.10</u>, the JCC shall be principally responsible for strategic oversight for the Commercialization of the Product in the Major Markets in accordance with the Combined Major Market Commercialization Plan. The JCC shall operate by the procedures set forth in <u>Section 2.10</u> and as of the Effective Date the joint commercialization team formed under the Collaboration Agreement shall disband and have no further role, rights, or responsibilities with respect to the Product.
- **2.4.2** <u>Specific Responsibilities</u>. Subject to the oversight of the JSC, the JCC shall be responsible for general oversight of Commercialization of the Product in the Major Markets, and to coordinate consistent messaging and branding across the Major Markets and, subject to <u>Section 2.1.3</u>, the Royalty Territory, including the following:
- (a) overseeing the development of a Major Market Commercial strategy for the Product, including goals and strategy for Product positioning and messaging, and preparation of an overall brand strategy for the Product (the "Global Brand Strategy"), and at a minimum annual updates thereto, which shall be consistent with the Combined Major Market Commercialization Plan, for review and approval by the JSC;
- **(b)** developing the core content for Promotional Materials for the Product for use in the Major Markets;
- (c) overseeing the development of goals and strategy for Product pricing and reimbursement for review and approval by the JSC, including recommending to the JSC target pricing bands for the Product both globally and regionally (with relevant regions recommended by the JCC) in the Territory, in compliance with Applicable Laws (including antitrust and competition laws), and monitoring Product pricing and reimbursement in the Territory;
- **(d)** overseeing the preparation of the Combined Major Market Commercialization Plan (including the budget therefor and the global Launch plan and Launch sequence contained therein) and annual updates and other amendments thereto, in each case, for review and approval by the JSC;
  - (e) monitoring compliance with the then-current budget included in

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the Combined Major Market Commercialization Plan;

- **(f)** monitoring progress under and overseeing the implementation of the Combined Major Market Commercialization Plan;
- (g) reviewing the Party Major Market Commercialization Plans and annual updates thereto for consistency, and confirming whether they are consistent, with the Combined Major Market Commercialization Plan (subject to  $\underline{Section 2.10.5(c)}$ );
- **(h)** reviewing and approving the US Coordination Plan relating to the Commercialization activities of the Parties in the United States incorporated into the SGI Major Market Commercialization Plan (and any updates or amendments thereto), subject to Section 3.5, including reviewing such plan and activities for consistency, and confirming that they are consistent, with the Combined Major Market Commercialization Plan, subject to Section 2.10.5(c), and monitoring compliance with the core job description and time periods for hiring Sales Representatives in the United States set forth in the US Coordination Plan;
- (i) reviewing the recommendations of the independent Third Party consultant engaged pursuant to Section 3.4 with respect to the total target headcount or number of FTEs for Sales Representatives in the United States and making a determination with respect to such allocation and deployment pursuant to Section 3.4 which shall be reflected in the US Coordination Plan;
- **(j)** reviewing and monitoring the forecasting of unit volume demand in the Territory for purposes of the Global Manufacturing Plan;
- **(k)** reviewing and monitoring Allowable Expenses and each Party's sales and financial reports pertaining thereto in coordination with the JFT;
- (I) facilitating the flow of information with respect to the Commercialization of the Product and coordinating such information flow with other Committees, as appropriate;
- **(m)** providing Quarterly updates on Commercialization activities in the Major Markets and the JCC's activities to the JSC; and
- **(n)** performing such other functions as the JSC may request from time to time or are expressly assigned to the JCC in this Agreement.

## **2.5** <u>Joint Finance Team.</u>

**2.5.1** <u>Formation and Purpose</u>. Genmab and SGI hereby establish a joint finance team (the "<u>Joint Finance Team</u>" or "<u>JFT</u>"), which shall consist of [\*] representatives from each Party (or such other equal number of representatives as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and <u>Sections 2.1</u> and <u>2.10</u>, the JFT shall provide support to all other Committees with respect to accounting and financial matters relating to the Collaboration and the Product. The JFT shall report directly to the JSC. The JFT shall operate by the procedures set forth in <u>Section 2.10</u>. Additionally, as of the Effective Date, the Financial

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Representatives (as defined in the Collaboration Agreement) shall be superseded and replaced by the JFT and shall have no further role, rights, or responsibilities with respect to the Product.

**2.5.2** Specific Responsibilities of the JFT. Subject to the oversight of the JSC,

the JFT shall:

(a) work with the other Committees and the Parties to assist in

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financial, budgeting and planning matters as required, including (i) assisting in the preparation of such reports on financial matters as are requested by the JSC for the implementation of the financial aspects of the Collaboration, and (ii) assisting with the preparation of budgets for the relevant Approved Plans;

- **(b)** agree on procedures, formats and timelines consistent with this Agreement for reporting financial data;
- **(c)** assist in resolving differences that relate to the financial terms of this Agreement; *provided*, that no Party shall be required to make any material change to its internal accounting and reporting systems and standards (as opposed to generating ad hoc or additional reports which the Parties shall generate upon reasonable request);
- **(d)** review each Party's reporting of financial data, including Net Sales and Allowable Expenses, under this Agreement;
- **(e)** facilitate the flow of financial information with respect to the Development, Commercialization and Manufacture of the Product in the Major Markets and coordinate such information flow with other Committees, as appropriate;
- (f) to the extent that the JSC and the JCMCT have approved Manufacturing by a Party, itself or through an Affiliate, in each case, pursuant to Section 6.3 or Section 6.4 (as appropriate), review and approve the amount of capital expenditures, including for plant and equipment, directly attributable or reasonably allocable to the Manufacture of Product for Commercialization by such Party or its Affiliate in the Major Markets and not accounted for in Manufacturing Costs or Commercial Packaging and Labeling Costs, as such amount is proposed by the JCMCT to be budgeted as an Allowable Expense in the Global Manufacturing Plan:
- (g) review and propose any changes to the FTE rates used to calculate FTE Costs for activities conducted under this Agreement with respect to the Product for review and approval by Party Written Consent; and
- **(h)** perform such other functions as the JSC may request from time to time or are expressly assigned to the JFT in this Agreement.

## **2.6** <u>Joint Chemistry, Manufacturing & Controls Team.</u>

**2.6.1** Formation and Purpose. Genmab and SGI have established a joint chemistry, manufacturing & controls committee pursuant to the Collaboration Agreement and wish to clarify and modify its role by way of forming a "Joint Chemistry, Manufacturing & Controls Team" or "JCMCT" hereunder solely for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein. The JCMCT shall consist of [\*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). Subject to the oversight of the JSC and Sections 2.1 and 2.10, the JCMCT shall oversee the Manufacture and supply of the Product globally, as well as all CMC Development activities and the global supply chain. The JCMCT shall operate by the procedures set forth in Section 2.10. For the avoidance of doubt, the specific allocation of responsibilities for Manufacturing activities between Genmab and SGI shall be made in

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accordance with <u>ARTICLE 6</u> and as of the Effective Date the joint chemistry, manufacturing & controls committee formed under the Collaboration Agreement shall be superseded and replaced by the JCMCT and shall disband and have no further role, rights, or responsibilities with respect to the Product.

- **2.6.2** Specific Responsibilities of the Joint Chemistry, Manufacturing & Controls Team. Subject to the oversight of the JSC, Sections 2.1 and 2.10, and ARTICLE 6, the JCMCT shall, in particular and in addition to its other responsibilities set forth in this Agreement:
- **(a)** oversee CMC Development activities and clinical and commercial Manufacturing of the Product;
- **(b)** with input from the JDC, JCC, and JFT, as necessary, oversee the preparation of an annual Global Manufacturing Plan (and budget therefor) for the Product, including, to the extent that the JSC and the JCMCT have approved Manufacturing by a Party, itself or through an Affiliate in accordance with <u>Section 6.3</u> or <u>Section 6.4</u> (as applicable), and proposing the amount of capital expenditures, including for plant and equipment, directly attributable or reasonably allocable to the Manufacture of Product for Commercialization in the Major Markets by such Party or its Affiliate and not accounted for in Manufacturing Costs or Commercial Packaging and Labeling Costs to be budgeted as an Allowable Expense, for review and approval by the JFT pursuant to <u>Section 2.5.2(f)</u>;
- **(c)** monitor compliance with the budget under the Global Manufacturing Plan for Manufacturing Commercial Supply, Manufacturing Clinical Supply and for CMC Development;
- **(d)** review and monitor Manufacturing Costs, CMC Development Costs, Commercial Packaging and Labeling Costs, and any other Manufacturing-related costs proposed for inclusion in Allowable Expenses or Development Costs;
- **(e)** oversee the preparation of submissions to Regulatory Authorities related to chemistry, manufacturing and controls ("<u>CMC</u>") matters;
- **(f)** oversee the preparation for and reviewing responses to regulatory inspections related to CMC aspects related to the Product, including the development of policies and procedures therefor;
- **(g)** oversee and monitor QA- and QC-related matters concerning the Product, including QA- and QC-related matters with respect to Post-Market Surveillance;
- **(h)** review and monitor Manufacturing processes and specifications for the Product, and to the extent agreed by the JCMCT, develop and implement continuous improvement or similar programs to promote Manufacturing quality and efficiency;
- (i) oversee Supply Chain Management, develop a global supply and risk mitigation strategy for the Product, and consider whether additional or alternative sourcing is necessary;

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- (j) facilitate the flow of information with respect to the Manufacture of the Product and coordinate such information flow with other Committees, as appropriate;
  - (k) provide Quarterly updates on the JCMCT's activities to the JSC; and
- (I) perform such other functions as the JSC may request from time to time or are expressly assigned to the JCMCT in this Agreement.

#### 2.7 <u>Joint Medical Affairs Team.</u>

- 2.7.1 <u>Formation and Purpose</u>. Genmab and SGI hereby agree to establish a joint medical affairs team solely for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein (the "<u>Joint Medical Affairs Team</u>" or "<u>JMAT</u>") within [\*] days after the Effective Date. The JMAT shall constitute a Working Group of the JDC and shall consist of [\*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). The JMAT shall report to the JDC; *provided*, *however*, that notwithstanding anything contained herein to the contrary, the Combined Major Market Medical Affairs Plan prepared by the JMAT and its corresponding budget, and any amendments thereto which shall be proposed by the JMAT, shall be submitted directly to the JSC for its review and approval pursuant to <u>Section 2.2.2</u>. Subject to the oversight of the JDC, <u>Sections 2.1</u> and <u>2.10</u>, and <u>ARTICLE 7</u>, the JMAT shall be responsible for strategic oversight of the Medical Affairs Activities in the Major Markets with respect to the Product under this Agreement, including coordination of such activities between the Parties. The JMAT shall operate by the procedures set forth in <u>Section 2.10</u>. For the avoidance of doubt, the specific allocation of responsibilities for Medical Affairs Activities between Genmab and SGI shall be made in accordance with ARTICLE 7.
- **2.7.2** <u>Specific Responsibilities of the Joint Medical Affairs Team</u>. Subject to <u>Sections 2.1</u> and <u>2.10</u>, and <u>ARTICLE 7</u>, the JMAT shall, in particular and in addition to its other responsibilities set forth in this Agreement:
- (a) oversee the preparation of the Combined Major Market Medical Affairs Plan (including the budget therefor) and annual updates and other amendments thereto;
- **(b)** monitor compliance with the then-current budget included in the Combined Major Market Medical Affairs Plan;
- (c) monitor progress under, and oversee the implementation of, the Combined Major Market Medical Affairs Plan, including with respect to named patient/compassionate use programs, grants, investigator-initiated and investigator-sponsored research for the Product, in each case, included in such plan;
- (d) review the Party Major Market Medical Affairs Plans and annual updates thereto for consistency with the Combined Major Market Medical Affairs Plan (subject to Section 2.10.5(c));
  - **(e)** review and approve the US Coordination Plan relating to the

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Medical Affairs Activities of the Parties in the United States incorporated into the SGI Major Market Medical Affairs Plan (and any updates or amendments thereto), subject to <u>Section 3.5</u>, and reviewing such plan and activities for consistency, and confirming that they are consistent, with the Combined Major Market Medical Affairs Plan, subject to <u>Section 2.10.5(c)</u>, and monitoring compliance with the core job description and time periods for hiring MSLs in the United States set forth in the US Coordination Plan;

- **(f)** review the recommendations of the independent Third Party consultant engaged pursuant to <u>Section 3.4</u> with respect to the total target headcount or number of FTEs for MSLs for the Product, allocation and deployment thereof in the United States and making a determination with respect to such allocation and deployment pursuant to <u>Section 3.4</u> which shall be reflected in the US Coordination Plan;
- **(g)** review, discuss and coordinate the Parties' global scientific presentation and publication strategy relating to the Product in accordance with this Agreement and the Publication Charter;
- **(h)** in coordination with the JDC prior to obtaining Regulatory Approval in a given jurisdiction and other Committees, as appropriate, develop a strategy for investigator-initiated trials and investigator-sponsored research in the Major Markets;
- (i) coordinate with the JDC with respect to the JDC's planning and conduct of Phase III-B Studies and Phase IV Studies;
- (j) facilitate the flow of information with respect to the Medical Affairs Activities for the Product in the Major Markets and coordinate the flow of such information with other Committees, as appropriate;
- **(k)** monitor Allowable Expenses for Medical Affairs Activities in coordination with the JFT;
- (I) provide Quarterly updates on Medical Affairs Activities in the Major Markets and the JMAT's activities to the JDC; and
- **(m)** perform such other functions as the JDC or JSC may request from time to time or are expressly assigned to the JMAT in this Agreement.

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## 2.8 Joint Regulatory Team.

- **2.8.1** Formation and Purpose. Genmab and SGI have established a joint regulatory team pursuant to the Collaboration Agreement and wish to clarify and modify its role by way of forming a "Joint Regulatory Team" or "JRT" hereunder solely for the purposes of activities related to the Product to be conducted under this Agreement as set forth herein. The Joint Regulatory Team shall constitute a Working Group of the JDC and consist of [\*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). The JRT shall report to the JDC. Subject to the oversight of the JDC, Sections 2.1 and 2.10, and ARTICLE 8, the JRT shall be principally responsible for strategic oversight and coordination of global regulatory activities with respect to the Product, except that the JCMCT will oversee CMC-related regulatory activities in coordination with the JRT, as applicable. For clarity, while the JDC will retain overall oversight of global regulatory activities with respect to the Product, the JRT will have the responsibilities for global regulatory activities with respect to the Product described in this Section 2.8. The JRT shall operate by the procedures set forth in Section 2.10 and as of the Effective Date the joint regulatory team formed under the Collaboration Agreement shall be superseded and replaced by the JRT and shall disband and have no further role, rights, or responsibilities with respect to the Product.
- **2.8.2** Specific Responsibilities of the Joint Regulatory Team. Subject to the oversight of the JDC, Sections 2.1 and 2.10, and ARTICLE 8, the JRT shall, in particular and in addition to its other responsibilities set forth in this Agreement:
- (a) discuss, prepare and submit to the JDC on an annual basis a Global Regulatory Plan or the regulatory portions of the Global Development Plan as contemplated by <u>Section 8.1.1</u> (which shall include a high-level summary prepared by SGI with respect to the Royalty Territory) describing the Parties' global regulatory strategy for the Product in the Territory which shall be incorporated into the Global Development Plan by the JDC and submitted to the JSC for approval;
- **(b)** monitor progress under, and oversee the implementation of, the Global Regulatory Plan;
- (c) review the Party Regulatory Plans and annual updates thereto for consistency with the Global Regulatory Plan as provided in <u>Section 8.1.1</u>;
- **(d)** consult with the JDC to develop the JDC's recommendations to the JSC regarding whether and when to submit a DAA, including a BLA, for the Product anywhere in the Territory;
- (e) subject to Section 8.1.6(a), in conjunction with the CDS Working Group, review the draft Core Data Sheet prepared by SGI and any amendments to the Core Data Sheet proposed by SGI, and agree on a proposed form of Core Data Sheet for submission to the JDC and ultimately review and approval by the JSC;
  - **(f)** provide Quarterly updates on the JRT's activities to the JDC; and

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- **(g)** perform such other functions as the JDC may request from time to time or are expressly assigned to the JRT in this Agreement.
- **2.9** CDS Working Group. Genmab and SGI hereby agree to establish a Core Data Sheet working group (the "CDS Working Group") within [\*] days after the Effective Date. The CDS Working Group shall constitute a Working Group of the JDC and consist of [\*] representatives from each Party (or such other equal number of representatives from each Party as may be agreed by mutual Party Written Consent). The CDS Working Group shall report to the JDC. Subject to Section 8.1.6(a), the CDS Working Group shall, in conjunction with the JRT, review the draft Core Data Sheet prepared by SGI and any amendments to the Core Data Sheet proposed by SGI, and agree on a proposed form of Core Data Sheet for submission to the JDC for review and approval, and ultimately submission by the JDC to the JSC for review and approval.

# 2.10 General Committee, Team, and Working Group Membership and Procedures.

- 2.10.1 Teams and Working Groups. From time to time, the JSC and the Committees may establish and delegate duties to working groups, teams, sub-teams, sub- committees or similar bodies formed under such Committee (each, a "Team" or a "Working Group") on an "as-needed" basis to oversee particular projects or activities, which delegations shall be reflected in the minutes of the meetings of the applicable Committee. Such Teams or Working Groups may be established on an ad hoc basis for purposes of a specific project, for the life of the Product or on such other basis as the establishing Committee may determine, and shall be constituted and shall operate as the establishing Committee may determine; provided, that (a) decision-making shall be [\*], with each Party's representatives on the applicable Team or Working Group collectively having [\*] on all matters brought before the Team or Working Group and (b) a Team or Working Group may not make any decision that is inconsistent with the Global Plans or Combined Major Market Plans unless an amendment to the applicable Global Plan or Combined Major Market Plan addressing such inconsistency is approved in accordance with this Agreement. Each Team and Working Group and their respective activities shall be subject to the oversight, review and approval of, and, shall report to, the Committee that established such Team or Working Group. In no event shall the authority of the Team or Working Group exceed that specified for the relevant Committee in this <u>ARTICLE 2</u>. Teams or Working Groups shall meet as needed to accomplish the objectives for which they were formed, and shall keep minutes of such meetings in accordance with Section 2.10.2. A Committee that forms a Team or Working Group shall have the ability to dissolve such Team or Working Group; provided, that (a) the JFT, JMAT and JCMCT are all to be deemed Teams established under the JSC for that purpose, and (b) the JRT is to be deemed a Team established under the JDC for that purpose.
- **2.10.2** <u>Committee Membership</u>. Each of Genmab and SGI shall designate representatives with appropriate expertise to serve as members of each Committee, Team, or Working Group and each representative may serve on more than one Committee, Team or Working Group as appropriate in view of the individual's expertise. Each Party may replace its Committee, Team, or Working Group representatives at any time upon written notice to the other Party. Each member of each Committee, Team, or Working Group shall be made aware of the Parties' obligation of compliance with all Applicable Laws, including antitrust and competition

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laws, as set forth in Section 9.1.5. Each Committee, Team, or Working Group shall have a chairperson; provided, that the chairperson for each Committee shall be staggered such that the chairperson for each Committee, Team, or Working Group shall alternate from one Party to the other Party annually. The initial chairperson of each of the Committees or Teams formed under this Agreement shall be a representative of a Party designated by the JSC. Each Party may change its designated chairpersons from time to time upon written notice to the other Party. The chairperson of each Committee, Team, or Working Group (or their respective designees), with assistance and guidance from the Alliance Managers, shall be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting of such Committee, Team, or Working Group; provided, that the Committee, Team, or Working Group chairpersons shall call a meeting of the applicable Committee promptly upon the written request of either Party to convene such a meeting. The then-current chairperson of each Committee, Team, or Working Group shall appoint its Alliance Manager to attend the meeting and record the minutes of the meeting in writing; provided, that such minutes shall be based on contemporaneous notes reflecting the substance of such meeting shared and mutually agreed between such Alliance Manager and the Alliance Manager or other representative of the other Party immediately following or as soon as practicable following such meeting. Notwithstanding the foregoing, such minutes shall be circulated to the other Party's Alliance Manager no later than [\*] following the meeting for review, comment and approval of the other Party. If no comments are received within [\*] of the receipt of the minutes by a Party, unless otherwise agreed, they shall be deemed to be approved by such Party. Furthermore, if the Parties are unable to reach agreement on the minutes within [\*] of the applicable meeting, the sections of the minutes which have been agreed between the Parties by that date shall be deemed approved and, in addition, each Party shall record in the same document its own version of those sections of the minutes on which the Parties were not able to agree.

Meetings. Each Committee, Team, or Working Group shall hold meetings at such times as it elects to do so, but in no event shall such meetings of each Committee be held less frequently than [\*] unless otherwise agreed by the JSC (provided, that a Committee, Team, or Working Group shall meet upon the reasonable request of a Party or any member thereof to discuss a matter within its purview). Each Committee shall meet alternately at a location designated by Genmab and a location designated by SGI, or at such other locations, including by audio or video teleconference as permitted below, as the Parties may agree. Except under exigent circumstances requiring Committee input, each Party will notify the other Party of proposed agenda items and provide appropriate information at least [\*] in advance of each meeting of the JSC and at least [\*] in advance of each meeting of any other Committee. The Alliance Managers (or their respective designees) shall attend meetings of each Committee as non-voting observers. Additional employees, consultants, and representatives of a Party may attend meetings of each Committee as non-voting observers; provided, that (a) any such employees, consultants or representatives are (i) under obligations to comply with all Applicable Laws (including antitrust and competition laws as set forth in Section 9.1.5), (ii) under obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in this Agreement and (iii) obligated to assign to the Parties any inventions made by any of them arising out of their participation in such meetings, and (b) with respect to non- employees of a Party, such attendance is subject to consent of the other Party. Each Party shall be responsible for all of its own expenses of participating on the Committees. Meetings of any Committee may be held by audio or video teleconference with the consent of each Party; provided, that (A) each Committee formed or initially organized under this Agreement as of the Effective

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Date will endeavor to meet by videoconference in lieu of audio-only teleconference to the extent reasonably practicable, and (B) the Parties will discuss in good faith holding at least [\*] meeting per year of each such Committee in person at a location alternately designated by Genmab and SGI (subject to travel restrictions, public health guidance and Applicable Law). No Committee shall take any action or make any decision except at a meeting properly called, and no action taken at any meeting of a Committee shall be effective unless a representative of each Party is present or participating. Subject to each Party's regulatory compliance policies and Applicable Law, the JMAT and the JCC may meet as a single body to discuss and exchange information if mutually agreed by such Committees or reasonably requested by either Party.

**2.10.4** Charter. Each Committee shall adopt a charter setting forth such additional rules and procedures as may be necessary for the performance of its responsibilities; *provided*, that such rules and procedures must be consistent with the terms of this Agreement. In the event of any conflict or inconsistency between any such Committee charter and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall govern and control.

## 2.10.5 <u>Decision-Making</u>.

- (a) <u>Decisions.</u> Decisions of each Committee, Team and Working Group shall be made by Joint Committee Consent, with each Party's representatives on a Committee, Team or Working Group collectively having [\*] on all matters brought before it; *provided*, that (i) Party Tactical Matters are subject to Section 2.10.6, (ii) any dispute between the Parties regarding the US Coordination Plan, including any decision or failure to reach consensus by a Committee, Team or Working Group regarding the US Coordination Plan shall be resolved in accordance with Section 3.5.2 (*provided* that any dispute regarding whether the US Coordination Plan is consistent with the Combined Major Market Plans shall be resolved pursuant to Section 2.10.5(c)), and (iii) each Committee's authority is limited as set forth in Section 2.1.3.
- Committee Dispute Resolution in General. Working Groups, Teams and Committees should make every effort to resolve disputes promptly without escalation. Any disagreement between the representatives of Genmab and SGI on any Working Group, Committee or Team as to matters within such Working Group, Team or Committee's purview (including, for clarity, whether a matter constitutes a Party Tactical Matter) shall, at the election of either Party, be referred for resolution as follows: (i) disputes between the representatives of Genmab and SGI on any Working Group or Team shall be referred for resolution to the applicable Committee to which it reports, and (ii) disputes between the representatives of Genmab and SGI on any Committee (including a dispute referred from a Working Group or Team to the applicable Committee that is not resolved within [\*] Business Days after such referral) shall be referred to the JSC for resolution. The Alliance Managers shall assist the relevant Committee in attempts to amicably resolve any such dispute in connection with the decision-making and dispute-resolution processes outlined in this Section 2.10.5 generally.
- (c) <u>Combined Major Market Plan Disputes</u>. Notwithstanding <u>Section 2.10.5(b)</u> above, the following principles shall apply to a Committee responsible under this Agreement for reviewing a Party Major Market Plan (including, if applicable, the US Coordination Plan incorporated therein pursuant to <u>Section 2.4.2(h)</u>, <u>Section 2.7.2(e)</u> or <u>Section 3.5.1</u>) for consistency with an applicable Combined Major Market Plan. Such reviewing

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Committee may consult with the relevant market-level and/or functional leads of each Party in connection with its review. If there is a dispute on such Committee regarding whether or not such Party Major Market Plan is consistent with the applicable Combined Major Market Plan and such dispute is not resolved within [\*] Business Days, the question of such Party Major Market Plan's consistency with the applicable Combined Major Market Plan shall be referred to the JSC for resolution. If the JSC determines that such Party Major Market Plan is consistent with the applicable Combined Major Market Plan (either as such Party Major Market Plan was presented to the JSC, or with any amendments requested by the JSC in order to make such Party Major Market Plan consistent with the applicable Combined Major Market Plan), the JSC's determination shall be binding on the Parties without further review by the Committee originally charged with reviewing such Party Major Market Plan; provided, that any subsequent amendment or update to such Party Major Market Plan shall be reviewed by such Committee for consistency, and confirmed by the Committee to be consistent, with the applicable Combined Major Market Plan (subject again to this Section 2.10.5(c)). If the JSC cannot agree on whether a Party Major Market Plan is consistent with the applicable Combined Major Market Plan or determines that a Party Major Market Plan is not consistent with the applicable Combined Major Market Plan (and the JSC cannot agree on amendments to such Party Major Market Plan that would make it consistent with the applicable Combined Major Market Plan), in each case, within [\*] Business Days of its referral to the JSC, such matter shall be referred to [\*] for resolution. If [\*] are unable to resolve the matter within [\*] Business Days after the matter is first referred to them, then [\*]. Any portion of the proposed Party Major Market Plan and corresponding budget that is not in dispute (i.e., not specifically subject to such dispute resolution process) will go into effect immediately notwithstanding such ongoing dispute resolution proceedings, and the portions of the most recently approved Party Major Market Plan and budget that correspond to the matters in dispute will be deemed to carry forward and apply to subsequent budget periods to the extent practicable, mutatis mutandis, until the resolution of such dispute, so as to minimize any disruption to the ongoing Development, Manufacturing, or Commercialization of the Product.

(d) <u>Disputes at the JSC</u>. Except for matters subject to <u>Section 2.10.5(c)</u>, any dispute or disagreement arising on the JSC as to matters within the JSC's purview or that are submitted to the JSC by another Committee in accordance with this Agreement for attempted resolution that are unable to be resolved within [\*] Business Days after the matter is first submitted to the JSC (or such other time period as may be agreed by the JSC) shall be referred to [\*] for resolution. If the [\*] are unable to resolve a matter within [\*] days after the matter is first referred to them, then [\*].

**2.10.6** Party Tactical Matters. Notwithstanding Section 2.10.5 or anything to the contrary contained in this Agreement or the Collaboration Agreement, but subject to this Section 2.10.6, Party Tactical Matters (a) with respect to the SGI Major Markets other than the United States shall be Party Tactical Matters of SGI and as such within the sole decision-making authority of SGI, (b) with respect to the Genmab Major Market shall be Party Tactical Matters of Genmab and as such within the sole decision-making authority of Genmab, (c) with respect to activities allocated to Genmab under the US Coordination Plan shall be Party Tactical Matters of Genmab and as such, subject to ARTICLE 3, within the sole decision-making authority of Genmab, and (d) except as provided in clause (c) above, with respect to all other activities in or for the United States shall be Party Tactical Matters of SGI and as such within the sole decision-making authority of SGI; provided, that (and so long as) all such decisions shall be consistent with the terms of this

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Agreement, the scope of such allocation or delegation of responsibility for the Major Markets, Applicable Law, the Global Plans, the Combined Major Market Plans, and the relevant Party Major Market Plans (including the US Coordination Plan). Subject to <u>Section 2.1.3</u> and this <u>Section 2.10.6</u>, Party Tactical Matters may be discussed by applicable Committee(s); *provided*, that a Party's decision with respect to its Party Tactical Matters (in the case of Genmab's activities in the United States, subject to the US Coordination Plan and <u>ARTICLE 3</u>) shall be final, and not subject to Committee decision-making or the dispute resolution procedures contained in this <u>Section 2.10</u>, <u>ARTICLE 16</u>, or elsewhere in this Agreement or the Collaboration Agreement.

**2.10.7** Exception for Urgent or Serious Safety Matters. Notwithstanding anything to the contrary in this Section 2.10, in the event of any dispute or disagreement arising on any Committee or otherwise between the Parties regarding an urgent or serious safety matter (including patient risk management and risk minimization events and safety issues that impact Product labeling) that a Party believes in good faith requires a determination on an expedited basis, then either Party may require that the dispute be referred to their respective safety officers (or similar functions) for the purpose of seeking to resolve the dispute on an expedited basis (including within, to the extent applicable, any timeframes required by Applicable Law). Such safety officers may designate an appropriate advisory group of each Party, as well as obtain any Third Party advice on their decision (with any such Third Parties to be bound by obligations of confidentiality at least as restrictive as those contained in this Agreement). If such safety officers are not able to resolve the dispute on any action referred to them [\*], within [\*] Business Days of such referral and at least [\*] Business Days in advance of any timeframes required by Applicable Law, [\*] with respect to such matter to the extent consistent with Applicable Law (including for clarity requirements of a Regulatory Authority).

## 2.11 Alliance Managers.

**2.11.1** Each of the Parties shall appoint one (1) representative who possesses a general understanding of biopharmaceutical Development, regulatory matters, Medical Affairs Activities, and Commercialization to act as its Alliance Manager in connection with the Collaboration (each, an "Alliance Manager"). The role of the Alliance Managers is to act as a single point of contact between the Parties to enable a successful Collaboration. The Alliance Managers (or their respective designees) may attend all meetings of any Committee, Team or Working Group and support the chairpersons of each Committee in the discharge of their responsibilities. An Alliance Manager (or designee) may bring any matter to the attention of any Committee, Team or Working Group if such Alliance Manager (or designee) reasonably believes that such matter warrants such attention. In addition, Alliance Managers (or their respective designees) may attend any joint meetings of the Parties regarding the Collaboration that are held independent of the Committees, Teams, or Working Groups.

**2.11.2** Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Each Party and its Alliance Manager may designate a substitute to temporarily perform the functions of Alliance Manager upon written notice to the other Party's Alliance Manager.

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# 2.12 Budgetary Matters.

- Prior to each regular meeting of the JSC and not less than Quarterly, the JFT shall prepare an analysis of actual Allowable Expenses and Development Costs incurred and Net Profit/Net Loss recorded by the Parties through the most recent date practicable in relation to the amounts budgeted therefor in the applicable Approved Plans. The JFT shall determine the frequency and timing of projections for each category described in the previous sentence, with the goal of accommodating each Party's corporate financial processes. Each Party shall provide to the JFT in a timely manner such information as the JFT may reasonably request for use in the preparation of such analysis; provided, that such information is in the possession of such Party. Each Party shall promptly notify the JFT in the event it anticipates any cost overrun with respect to Development Costs and/or Allowable Expenses in a given functional area (e.q., Medical Affairs Activities or Commercialization activities) incurred or to be incurred by it with respect to any Year or any material variation in Net Sales amounts from the amounts projected in the Approved Plans. The JFT shall promptly review any actual or projected cost overrun that is reported to it and thereafter shall, in conjunction with the JSC, consider and recommend to the JSC for approval either (a) an appropriate variance to the applicable Approved Plans, which variance, if approved by the JSC, shall be considered a part of the Approved Plans or (b) such other amendments to the Approved Plans as may be necessary or appropriate to bring the operation of the Collaboration within the budgetary guidelines set forth in the Approved Plans; provided, that the JSC shall approve such variance unless such cost overrun exceeds the lower of [\*] of the budgeted amount for a given functional area (e.g., Medical Affairs Activities or Commercialization activities) in a given Year, in which case the JSC may elect not to approve the variance or amend the applicable Approved Plan. If the JSC does not approve such variance or does not amend the applicable Approved Plan, [\*], and such expense shall [\*].
- **2.12.2** In order to facilitate planning and budgetary control by the relevant Committees and the Parties, each Party shall provide to the JFT and to the other Party not later than [\*] after the end of each Quarter a projection (representing a good faith estimate) of the Allowable Expenses it expects to incur and the Net Sales it expects to record in its Major Markets and the Development Costs it expects to incur, in each case, in such Ouarter.

#### ARTICLE 3 GENMAB CO-PROMOTION

- 3.1 Genmab Right to Co-Promote and Provide Medical Affairs Efforts.
- **3.1.1** <u>Genmab U.S. Co-Promotion Rights</u>. Notwithstanding anything to the contrary contained in this Agreement, but without prejudice to the status of the United States as an SGI Major Market, the Parties agree that Genmab will be SGI's co-promotion and medical affairs partner with respect to the Product in the United States on the terms and subject to the conditions contained in this <u>ARTICLE 3</u>. In particular, Genmab will provide with respect to the Product in the United States:
- **(a)** the Sales Representatives as described in <u>Section 1</u> of **Schedule 3.1** to Promote the Product in the United States;

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- **(b)** the MSLs described in <u>Section 2</u> of **Schedule 3.1** to engage in in- depth dialogues with physicians or other HCPs regarding medical issues associated with the Product; and
- (c) FTEs for [\*] management of such Sales Representatives and MSLs as described in <u>Section 3</u> of **Schedule 3.1** (collectively, "<u>Genmab Managers</u>");

in each case ((a) through (c)), as more fully described in this ARTICLE 3.

The Sales Representatives contemplated by <u>Section 3.1.1</u> are referred to herein as "<u>Genmab Sales Representatives</u>," the MSLs contemplated by <u>Section 3.1.1</u> are referred to herein as "<u>Genmab MSLs</u>," and the Genmab Sales Representatives, Genmab MSLs and Genmab Managers are referred to herein, collectively, as "<u>Genmab US Personnel</u>."

- **3.1.2** <u>Genmab US Activities</u>. All activities undertaken by the Genmab US Personnel with respect to the Product in or for the United States (collectively, the "<u>Genmab US Activities</u>") will be subject to and taken in accordance with the SGI Major Market Commercialization Plan, the SGI Major Market Medical Affairs Plan, the US Coordination Plan, and this ARTICLE 3.
- **3.1.3** <u>SGI Rights</u>. The rights and responsibilities of SGI with respect to Commercialization and Medical Affairs Activities for the Product in the United States will remain the same as elsewhere in the SGI Major Markets except as explicitly stated in this <u>ARTICLE 3</u>. In particular, subject only to the consistency of SGI's Party Major Market Plans with the applicable Combined Major Market Plans, the US Coordination Plan, and the terms and conditions of this Agreement, SGI will have authority and responsibility for:
- subject to [\*], [\*] for the Product in the United States [\*] in accordance with this Agreement;
- **(b)** subject to consistency with [\*] the terms of this Agreement [\*] with respect to the Product in the United States; and
- **(c)** subject to [\*] and consistency with [\*] the terms of this Agreement, [\*] with respect to the Product in the United States.
- **3.1.4** <u>Limitations on Genmab Activities</u>. Except to the extent expressly provided in the US Coordination Plan or otherwise with the prior written authorization of SGI, Genmab shall have no independent right or authority to, and shall not, through the Genmab US Personnel or otherwise, with respect to the Product in or for the United States:
  - (a) conduct any form of [\*] or [\*]; or
  - **(b)** conduct any [\*] or other activities [\*].
  - **3.1.5** Genmab Activities. To the extent expressly provided in the US

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Coordination Plan or otherwise with the prior written authorization of SGI, Genmab may, through the Genmab US Personnel, with respect to the Product in or for the United States:

- (a) participate in and provide input on [\*], or similar activity, whether [\*] or [\*], and Genmab may [\*] in accordance with this Agreement and [\*];
- **(b)** participate in and provide input as to [\*], including [\*] with respect to the Product for the United States;
- **(c)** participate in and provide input on and support for [\*], or similar activity, [\*] with respect to the Product for the United States;
  - **(d)** provide [\*] or [\*] regarding the Product;
  - **(e)** authorize, support or facilitate [\*], or otherwise [\*];
  - **(f)** participate in and provide input on and support for [\*] with respect to the

Product:

- (g) retain, engage, or otherwise contract with [\*]; or
- **(h)** [\*] or [\*], in each case, to the extent that [\*] have been approved by SGI.

The Parties agree that each Party's role in the co-Promotion of and Medical Affairs Activities for the Product in the United States will be conducted only as set forth in [\*]. Notwithstanding the foregoing, [\*] (provided that such decisions are consistent with the US Coordination Plan and this <u>ARTICLE 3</u>), but, for the avoidance of doubt, [\*] in the United States shall not include decisions [\*] as set forth in the [\*] or this <u>ARTICLE 3</u>.

- **3.1.6** <u>Genmab Collaboration</u>. Following the Effective Date and so long as the Product has obtained Regulatory Approval for only one Disease in the United States, the Parties will each designate a [\*] to interact for non-field coordination. Each Party will [\*] for its [\*]. In connection with obtaining Regulatory Approval in the United States for a second or subsequent Diseases, the Parties will discuss and consider in good faith whether to add further personnel to serve as, and/or to [\*] for, [\*]. For clarity, the [\*] shall not be assigned to or perform services at any facility of [\*] or its [\*] and each Party acknowledges and agrees that the [\*] and [\*] are not, are not intended to be, and will not be treated as, employees of [\*] for any purpose.
- **3.2** <u>Co-Promotion in the United States</u>. The Parties agree that the activities of their Sales Representatives and MSLs for the Product in the United States for each Disease for which Regulatory Approval is obtained will be conducted consistent with the following:
- **3.2.1** activities to be conducted by each Party's Sales Representatives and MSLs will be allocated in a manner consistent with <u>Section 3.4</u>;
- **3.2.2** at a minimum, [\*] related to the Launch of the Product for a Disease in the United States will be jointly attended by the Parties' personnel performing such co-Promotion

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activities and Medical Affairs Activities;

- **3.2.3** the Parties will share information related to the activities of their Sales Representatives and MSLs for the Product in the United States, including to the extent applicable in relation to [\*], on a timely and recurring basis and in any event, upon the reasonable request of the JCC or JMAT, as applicable, or the other Party; and
- **3.2.4** as of the Effective Date and so long as the Product has obtained Regulatory Approval for only one Disease in the United States, each Party will provide an equal number of Sales Representatives in the United States who will be dedicated solely to the Product and such Disease, and consistent with <u>Section 1.34</u>, "Details" for purposes of this Agreement will include only Primary Position Details; *provided*, that in connection with the Launch of the Product for a second or subsequent Disease in the United States, the Parties may agree to amend the Agreement to include Secondary Position Details as "Details" hereunder, in which case the Parties shall also review and determine the terms and conditions applicable to Primary Position Details and Secondary Position Details under this Agreement and, if applicable, Sales Representative FTEs, including for example methods to assess performance against key performance indicators.
- 3.3 Performance of US Activities. Each Party will hire and maintain Sales Representatives and MSLs of sufficient number and expertise to permit such Party to fully perform the activities allocated to it for the United States under this ARTICLE 3, in each case, in accordance with the core job descriptions and time periods set forth in the US Coordination Plan. Compliance with such criteria will be monitored by the JCC with respect to Sales Representatives pursuant to Section 2.4.2(h) and by the JMAT with respect to MSLs pursuant to Section 2.7.2(e). If either Party fails at any time to meet the applicable hiring goals or maintain the agreed level of Sales Representatives and MSLs as set forth in the US Coordination Plan (including a failure to satisfy the criteria set forth in the applicable core job description), it shall, at its own cost and expense, provide a plan to the JCC and/or JMAT, respectively, designed to remedy such failure expeditiously, and then take such actions as are reasonably necessary to cure any such failure as promptly as practicable, such as by offering hiring bonuses or other incentives, [\*], as applicable. If any such failure to meet its applicable hiring goals or maintain the agreed level of Sales Representatives and MSLs as set forth in the US Coordination Plan, as applicable, continues without cure for (a) more than [\*] days or (b) more than [\*] days during the [\*] prior to the anticipated first Launch of the Product in the United States, the other Party may, in its sole discretion, elect to assume responsibility for and provide Sales Representatives or MSLs to perform activities allocated to the first Party under the US Coordination Plan, to the extent of such failure. If the first Party disputes whether it failed to satisfy the hiring goals or cure any such failure, it may submit such failure to the JSC for resolution; provided, that the other Party shall be permitted to provide such Sales Representatives and MSLs and perform such activities pending the resolution of any such dispute. If the first Party cures any failure to satisfy such hiring goals or to maintain the agreed level of Sales Representatives and MSLs after the time periods described in clauses (a) or (b) and such cure is confirmed by the JCC or JMAT, as applicable, [\*], and the Parties shall [\*]. Without limiting the foregoing, the Parties acting through the JCC or JMAT, as applicable, shall mutually consider the [\*] set forth in the Combined Major Market Commercialization Plan and Combined Major Market Medical Affairs Plan, as applicable, and agree on [\*].

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Size and Deployment of Sales Representatives and MSLs in the United States. Except as otherwise mutually agreed by the Parties through the JSC, the Parties shall engage a mutually agreed independent Third Party consultant with requisite expertise regarding the commercialization of pharmaceutical products and therapies (such as [\*]) to: (a) recommend options for [\*] for Sales Representatives and MSLs for the Product in the United States and (b) propose options for Sales Representative and MSL FTEs [\*] within the United States for the Product in the United States with the goal of equitably sharing responsibilities between the Sales Representatives and MSLs of both Parties consistent with each Party's respective fifty percent (50%) share of the total Sales Representative and MSL FTEs for the Product in the United States as set forth on Schedule 3.1, in each case of (a) and (b), for the Parties to [\*]. The Parties shall engage in such process both initially in anticipation of first Regulatory Approval of the Product in the United States, and additionally in anticipation of each subsequent Regulatory Approval of the Product in the United States for additional Disease(s). The recommendations of such independent Third Party consultant with respect to the [\*] of Sales Representative and MSL FTEs in the United States shall be taken [\*], which shall make determinations with respect to such [\*] Sales Representatives and MSLs pursuant to Section 2.4.2(i) and Section 2.7.2(f), respectively. The recommendations of such independent Third Party consultant with respect to [\*] of Sales Representative and MSL FTEs in the United States shall be taken [\*] by [\*], which shall make a determination with respect to such Sales Representative and MSL FTEs in the United States in its [\*] in advance of the anticipated Regulatory Approval of the Product in the United States for a given Disease; provided, that such [\*] of Sales Representative and MSL FTEs selected by [\*] shall fall within the [\*] for Sales Representative and MSL FTEs agreed by [\*] or by [\*], as applicable.

## 3.5 US Coordination Plan.

In General. SGI, in collaboration with Genmab as provided in this Section 3.5.1 3.5.1, will prepare a plan describing (a) the sales and marketing plans for the Product in the United States, (b) the activities to be performed by the Parties' Sales Representatives and MSLs with respect to the Product in or for the United States, (c) a mechanism to ensure that the Parties hire and maintain Sales Representatives and MSLs of sufficient number and expertise to permit the Parties to fully perform the activities allocated to them under this ARTICLE 3, including core job descriptions (e.g., responsibilities, core competencies, experience and other qualifications), a methodology for demonstrating proficiency, time points at which progress against hiring goals will be measured, (d) procedures for monitoring Sales Representatives and MSLs in the United States, and (e) training programs for such Sales Representatives and MSLs (the "US Coordination Plan"). SGI will provide an initial draft of the US Coordination Plan to Genmab for its review and comment for a period of not less than [\*] Business Days. Genmab's representatives on the JCC and JMAT, respectively, will work with SGI's representatives on such Committees to develop the US Coordination Plan relating to the Commercialization activities (for the JCC) and Medical Affairs Activities (for the JMAT) of the Parties under this <u>ARTICLE 3</u> with respect to the Product in or for the United States, respectively, and the US Coordination Plan will be subject to JCC and JMAT approval pursuant to Sections 2.4.2(h) and 2.7.2(e), respectively. SGI shall update the initial US Coordination Plan on an annual basis (or more frequently as directed by the JCC). For each such update, Genmab shall have not less than [\*] Business Days to review and comment thereon. Such updated US Coordination Plan will be subject to JCC and JMAT approval pursuant to Sections 2.4.2(h) and 2.7.2(e), respectively. The US Coordination Plan will be incorporated into the SGI Major Market Commercialization Plan

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and the SGI Major Market Medical Affairs Plan, as applicable. Accordingly, the US Coordination Plan will be consistent with the Combined Major Market Commercialization Plan and the Combined Major Market Medical Affairs Plan, as applicable, and the strategic matters described therein, and will be reviewed for consistency, and confirmed to be consistent, with the Combined Major Market Plans by the JCC and JMAT, respectively. For clarity, the US Coordination Plan will include a stand-alone budget, and the activities contemplated by the US Coordination Plan will be included in the applicable budgets under the SGI Major Market Commercialization Plan and SGI Major Market Medical Affairs Plan, as applicable.

**3.5.2** <u>US Coordination Plan Disputes.</u> Notwithstanding SGI's role as the Selling Party in the United States and that the United States is a SGI Major Market country, it is agreed and acknowledged that the US Coordination Plan (and any material updates or amendments thereto) shall be subject to review and approval of the JCC and JMAT pursuant to <u>Sections 2.4.2(h)</u> and <u>2.7.2(e)</u>, respectively. However, in the event of any dispute between the Parties regarding the US Coordination Plan that is not a Party Tactical Matter (which is to be resolved pursuant to Section 2.10.6) or a dispute regarding whether the US Coordination Plan is consistent with an applicable Combined Major Market Plan (which is to be resolved pursuant to Section 2.10.5(c)), including any failure despite good faith efforts by the Parties' representatives on the JCC or JMAT to approve or otherwise reach consensus on any aspect of the US Coordination Plan after the US Coordination Plan is first presented to such Committee, the Parties (through their representatives on the relevant Committee) will endeavor in good faith to amicably resolve the dispute as promptly as practicable, but if such dispute is not resolved within [\*] Business Days of the US Coordination Plan first being referred to the JCC or JMAT, as applicable, then such matter (which shall be limited to only that portion of the US Coordination Plan in dispute) will be submitted for resolution to the JSC. Upon request by either Party made during such [\*] Business Day period, the Parties' respective Chief Executive Officers (or their delegates mandated with equivalent decision-making authority) shall during such [\*] Business Day period discuss any such matter that is material to either Party or the Collaboration. If the JSC does not resolve such matter within [\*] Business Days after the matter is first referred to it, then SGI shall have final decision-making authority over the matter(s) in dispute and the contents of the US Coordination Plan, subject only to consistency of the US Coordination Plan with the Combined Major Market Commercialization Plan and/or the Combined Major Market Medical Affairs Plan, as applicable, as required under Section 3.5.1. For clarity, SGI's final decisionmaking authority under this Section 3.5.2 shall be final and is not be subject to dispute resolution under Section 2.10.5 or ARTICLE 16, except to the extent Section 2.10.5(c) applies with respect to consistency of the US Commercialization Plan with the Combined Major Market Commercialization Plan and/or the Combined Major Market Medical Affairs Plan, as applicable. During the pendency of any dispute regarding the US Coordination Plan, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder in good faith and, to the extent practicable, maintain the status quo and operate under the last approved US Coordination Plan (if applicable) until resolution of the relevant dispute or approval of the US Coordination Plan.

## **3.6** Compliance and Training.

**3.6.1** <u>In General</u>. All Genmab US Activities as well as Promotional activities and

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Medical Affairs Activities conducted by SGI in the United States shall be undertaken in accordance with (a) all Applicable Laws and (b) notwithstanding anything contained herein or the Collaboration Agreement to the contrary, the compliance practices, policies and procedures of SGI (as to Genmab, to the extent such practices, policies and procedures are communicated to Genmab or the Genmab US Personnel); *provided, however*, that neither Party or its personnel will be required to undertake any obligation in connection with such activities to the extent that such Party reasonably believes in good faith that such activities violate or are reasonably likely to violate Applicable Law or such Party's written policies regarding the promotion of pharmaceutical products (and any such deviations made by a Party shall not be considered a material breach of this Agreement). For the avoidance of doubt, the preceding sentence shall not entitle [\*]. Genmab agrees to use Commercially Reasonable Efforts to make available to SGI, upon SGI's reasonable request, such information regarding the [\*] in or for the United States as may be provided in the US Coordination Plan or otherwise reasonably required in order for SGI to Commercialize the Product in the United States and monitor compliance with this Agreement and Applicable Law.

- **3.6.2** Training. All Genmab US Personnel and SGI personnel performing Promotion and Medical Affairs Activities for the Product in the United States must complete, prior to performing such activities and on an ongoing basis, the applicable mandatory training program(s) developed by SGI and described in the US Coordination Plan. Each Party may conduct such other non-mandatory training for its personnel performing such activities as it determines at its sole cost and expense (*i.e.*, the expenses thereof shall not be included in Allowable Expenses); *provided*, that Genmab shall permit a representative of SGI to attend such other non-mandatory Product-related training (such attendance of such SGI representative to be at SGI's sole cost and expense, and not included in Allowable Expenses) and SGI shall permit a representative of Genmab to attend such other non-mandatory Product-related training (such attendance of such Genmab representative to be at Genmab's sole cost and expense, and not included in Allowable Expenses).
- **3.6.3** Promotional Materials. In connection with the Genmab US Activities, unless otherwise agreed by the Parties by mutual Party Written Consent, Genmab [\*]; *provided*, that such Promotional Materials shall in all cases be consistent with (a) the core content for Promotional Materials prepared by the JCC and approved by the JSC pursuant to Section 2.4.2(b), (b) the Approved Plans, and (c) the Product labeling approved by the FDA. Without limiting the foregoing, Genmab will have a reasonable opportunity (not less than [\*] Business Days) through the Committees or otherwise to [\*] (and [\*] shall in good faith consider any comments provided by [\*]) before such Promotional Materials are finally approved by [\*].

# 3.7 <u>Miscellaneous</u>.

- **3.7.1** <u>Genmab Diligence</u>. Genmab shall use Commercially Reasonable Efforts to conduct the Genmab US Activities allocated to Genmab US Personnel in the US Coordination Plan, SGI Major Market Commercialization Plan, SGI Major Market Medical Affairs Plan, or otherwise under this Agreement.
- **3.7.2** <u>Invoicing and Booking of Sales</u>. [\*] may not accept [\*], and if [\*] receives any [\*] in or for the United States, it shall refer such [\*] for acceptance or rejection.

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- **3.7.3** <u>No Sublicensing or Subcontracting.</u> [\*] may not [\*] any Genmab US Activities, in whole or in part, to any [\*] without [\*] prior written consent.
- **3.7.4** <u>No Other Co-Promotion or Participation Rights.</u> Except as expressly contemplated with respect to the Genmab US Activities under this <u>ARTICLE 3</u>, neither Party will have the right to Promote, co-Promote, or otherwise conduct or participate in Commercialization activities, Medical Affairs Activities, or similar activities with respect to the Product in the other Party's Party Major Market(s).
- **3.7.5** Responsibility for Acts and Omission of Personnel. Each Party shall be solely responsible for: (a) the acts and omissions of its Sales Representatives, MSLs, and other personnel while performing any of the activities to be performed by such Party under this Agreement; and (b) all disciplinary, probationary and termination actions taken by it, as well as for the formulation, content, and for the dissemination (including content) of all human resources policies and rules (including written disciplinary, probationary and termination policies) applicable to any members of its personnel. Each Party shall comply with all Applicable Laws in the hiring, employment, and discharge of all members of its personnel.
- 3.7.6 Employment of Personnel. Each Party acknowledges and agrees that all matters of compensation, benefits and other terms of employment for all personnel of such Party are solely between such Party or its Affiliate and such individual. Each Party shall be solely responsible and liable for the payment of all compensation and benefits to its employees and any other members of its field force, and each Party acknowledges and agrees that neither Party will maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of the other Party or its personnel, all of which shall be the sole responsibility of the Party to which such person is employed or engaged. Without limiting the foregoing, a Party shall not be responsible to the other Party, or to any member of the other Party's field force (or any other personnel), for any compensation, expense reimbursements, benefits, or payroll-related taxes or withholdings that may be imposed upon or be related to the performance by individuals employed or engaged by such other Party, all of which shall be the sole responsibility of the Party to which such person is employed or engaged, even if it is subsequently determined by any court or Governmental Authority that any such individual may be an employee or a common law employee of the other Party or any of its Affiliates, or is otherwise entitled to such payments and benefits.
- **3.7.7** Non-Compliance by Field Force. In the event that a Party has a reasonable basis for believing (*i.e.*, based on evidence or other reasonable substantiation) that any personnel of the other Party or any of its Affiliates may have violated any Applicable Law or failed to comply with this Agreement or the US Coordination Plan, or is otherwise damaging relationships with any health care professional or health care organization, or the Product brand, in each case, in connection with activities performed by such personnel in the United States pursuant to this Agreement, then such Party shall promptly notify the other Party in writing of such belief and the basis therefor. Following such notification and a reasonable opportunity to investigate the relevant facts, the Parties shall meet to discuss such belief and basis. The notified Party shall take such actions as are reasonable under the circumstances in response to the notifying Party's justified concerns, including, if necessary, excluding such individual from Product-related activities. For

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clarity, the foregoing shall not limit any rights or remedies of a Party hereunder.

## **3.7.8** Termination of U.S. Rights.

- **(a)** Genmab may terminate its rights and activities with respect to the Product in the United States under this <u>ARTICLE 3</u> by providing SGI at least [\*] prior written notice. Any such termination shall be with respect to Genmab's rights under this <u>ARTICLE 3</u> in their entirety.
- (b) In the event that Genmab exercises its right to terminate its activities with respect to the Product in the United States under Section 3.7.8(a), Genmab shall promptly (and in any event within [\*] of such termination) wind down, discontinue and terminate all activities undertaken or to be undertaken, directly or indirectly, by Genmab, its Affiliates, or Genmab US Personnel with respect to the Product in the United States, in each case, in an orderly manner consistent with Applicable Law. Without limiting the foregoing, the Parties will discuss in good faith and endeavor to agree on a transition plan for such wind down and termination through the JCC and JSC, such agreement not to be unreasonably withheld, conditioned, or delayed. Without limiting any rights of SGI contemplated by this ARTICLE 3, following any termination of Genmab's rights under this Section 3.7.8(b), SGI shall have no further obligations under this ARTICLE 3, including any obligation to prepare a US Coordination Plan. For clarity, after any such termination of Genmab's rights under this Section 3.7.8(b), the Parties' rights and obligations with respect to the Product in the United States will be consistent with their rights and obligations with respect to the Product in any other SGI Major Market.

# ARTICLE 4 COMMERCIALIZATION; FURTHER DEVELOPMENT

**4.1** Commercialization in Major Markets Generally. Subject to the terms and conditions of this Agreement, including Genmab's rights with respect to the United States under ARTICLE 3, (a) SGI shall have the sole and exclusive right to Commercialize the Product in the SGI Major Markets or any portion thereof consistent with an annual Commercialization plan and budget for the SGI Major Markets prepared by SGI in accordance with Section 4.3.1 (such plan and budget, collectively, the "SGI Major Market Commercialization <u>Plan</u>"), and (b) Genmab shall have the sole and exclusive right to Commercialize the Product in the Genmab Major Market or any portion thereof consistent with an annual Commercialization plan and budget for the Genmab Major Market prepared by Genmab in accordance with Section 4.3.1 (such plan and budget, collectively, the "Genmab Major Market Commercialization Plan"); provided, in each case ((a) and (b)), that such Party Major Market Commercialization Plans shall be consistent with the annual Combined Major Market Commercialization Plan, including the corresponding budget therein, prepared by the Parties and approved by the JSC in accordance with <u>Section 4.2</u> (such plan and budget, collectively, the "<u>Combined Major</u> Market Commercialization Plan"). In the event of (i) any inconsistency between the Combined Major Market Commercialization Plan and this Agreement, the terms of this Agreement shall prevail, and (ii) any inconsistency between a Party Major Market Commercialization Plan and the Combined Major Market Commercialization Plan, the terms of the Combined Major Market Commercialization Plan shall prevail.

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# 4.2 <u>Combined Major Market Commercialization Plan.</u>

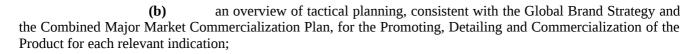
Generally. The Combined Major Market Commercialization Plan will set forth the Parties' mutually agreed: (a) Commercialization strategy and resourcing plans with respect to the Product (including with respect to strategic imperatives, branding, positioning, campaign and messaging platforms) in the Major Markets; (b) anticipated performance obligations and funding requirements for the Commercialization of the Product in the Major Markets; (c) target pricing bands for the Product both globally and regionally (with relevant regions recommended by the JCC) in the Territory; (d) reimbursement strategy for the Product in the Major Markets: (e) global Launch plan and Launch sequence for the Product in the Territory: (f) budget for activities contemplated by the Combined Major Market Commercialization Plan, including anticipated Sales Representatives and other personnel conducting Commercialization activities for the Product; (g) an agreed range for the aggregate number of Sales Representatives expected to be deployed in the Major Markets either by country or region as reasonably determined by the JCC; (h) key performance indicators either by country or region, as reasonably determined by the JCC, that the Parties shall implement, and that shall apply to the activities of the Sales Representatives of each Party in the Major Markets to monitor and assess Product performance, such as sales, attitudes, trial and usage market research, vial volume, and, to the extent such information is reasonably available, total prescriptions, new patient starts, sales, first claim fill rates, and prescription duration, and (i) [\*] forecasts and projections for an additional [\*] for such topics included in the Combined Major Market Commercialization Plan; in each case of (a)-(i), for the Major Markets except as otherwise indicated. The topics included in the Combined Major Market Commercialization Plan will be presented both on a global basis across all Major Markets and on a regional or Major Market-by-Major Market basis as reasonably determined by the JCC. For the avoidance of doubt, the Combined Major Market Commercialization Plan will contain detailed strategic plans and, where applicable, budgets for the elements set forth in clauses (a)-(i) above for each region or Major Market as determined by the JCC, and each Party's Party Major Market Commercialization Plan will be consistent with the overall plan and budget for each of the relevant region(s) or Major Market(s) contained in the Combined Major Market Commercialization Plan. The Combined Major Market Commercialization Plan and each amendment or annual update thereto shall reflect each Party's good faith estimate of its anticipated Commercialization commitments for each of the relevant region(s) or Major Market(s).

4.2.2 <u>Initial Combined Major Market Commercialization Plan and Annual Updates</u>. The Parties shall jointly prepare an initial draft of the Combined Major Market Commercialization Plan which shall be submitted to the JCC for review and approval at least [\*] prior to the first anticipated Launch of the Product in a Major Market (as such date is determined by the JDC) and cover such period (including forecasts and projections) as determined by the JCC. Once agreed by the JCC, the JCC shall recommend the Combined Major Market Commercialization Plan to the JSC for approval. The Combined Major Market Commercialization Plan shall be updated at least [\*], and all updates and amendments shall be reviewed and approved by the JCC and then submitted to the JSC for approval. The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees.

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- 4.3 <u>Commercialization by each Party in its Party Major Market(s)</u>.
- **4.3.1** Generally. Subject to the terms and conditions of this Agreement, including Genmab's rights in the United States under <u>ARTICLE 3</u>, each Party (itself or through its Affiliates or (sub)licensees as otherwise permitted herein) shall have the right to Commercialize the Product in its Party Major Market(s) or any portion thereof, including by performing activities for such Party Major Market(s) as follows: (a) preparing Promotional Materials for use in its Party Major Market(s) (*provided*, that such materials are consistent with the core content approved by the JSC), (b) preparing training materials and training programs for personnel engaged in such Commercialization activities, and implementing such training, and (c) making decisions with respect to its Party Tactical Matters in connection with such Commercialization activities; *provided*, that, in each case ((a) through (c)), such activities shall be consistent with the Party Major Market Commercialization Plan, Combined Major Market Commercialization Plan, and US Coordination Plan, including the tactical and strategic matters described in such plans, and otherwise conducted in accordance with this Agreement (including <u>ARTICLE 3</u> with respect to the United States).
- Party Major Market Commercialization Plans. Each Party will prepare a Party Major Market Commercialization Plan for its respective Party Major Market(s) that is consistent with the Combined Major Market Commercialization Plan, which Party Major Market Commercialization Plan covers the same time period addressed by such Combined Major Market Commercialization Plan. The Genmab Major Market Commercialization Plan and the SGI Major Market Commercialization Plan will each describe the plan for Commercialization of the Product in the applicable Party Major Market(s), specify in reasonable detail the Commercialization activities to be performed by or on behalf of the applicable Party for the Product in the applicable Party Major Market(s), and include a budget for such Party's Commercialization activities to be conducted in its Party Major Market(s). In addition, the SGI Major Market Commercialization Plan will incorporate the Commercialization activities set forth in the US Coordination Plan. Each Party shall prepare its own Party Major Market Commercialization Plan and provide it to the JCC, which shall review such plans for consistency with the Combined Major Market Commercialization Plan (subject to Section 2.10.5(c)). The initial draft of each Party Major Market Commercialization Plan shall be submitted to the JCC within [\*] after submission to the JSC of the initial draft of the Combined Major Market Commercialization Plan by the JCC in accordance with Section 4.2.2. The Party Major Market Commercialization Plans shall be updated at least annually, and all updates and amendments shall be reviewed and approved by the JCC for consistency with the Combined Major Market Commercialization Plan (subject to Section 2.10.5(c)). The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees. Each Party Major Market Commercialization Plan shall include with respect to the Product and the relevant Party's Party Major Market(s), as applicable and as consistent with the Combined Major Market Commercialization Plan:
  - (a) an executive summary:

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- **(c)** an overview of plans for the number, structure and deployment of Sales Representatives and other personnel conducting Commercialization activities for the Product by geography, target audience, activities, or other relevant criteria;
- **(d)** an overview of (i) market research plans and market assessments and (ii) general plans for the marketing, Promotion and sale of the Product, with appropriate input as to financial matters from the JFT;
- **(e)** a market, unit sales, and Net Sales forecast (*provided*, for clarity, that the Parties are not required to mutually agree on a Net Sales forecast or a Net Profit/Net Loss forecast, but, if relevant, they will cooperate with respect to preparing such forecasts in accordance with <u>Section 5.1.2(d)</u>);
- **(f)** an overview of pricing and discounting strategies for the applicable Party Major Market(s) consistent with <u>Section 2.4.2(c)</u>; and
- **(g)** key performance indicators to monitor and assess Product performance consistent with the key performance indicators set forth in the Combined Major Market Commercialization Plan.
- **4.3.3** <u>Commercialization Diligence in the Major Markets</u>. Following the receipt of relevant Regulatory Approvals in relevant country(ies), each Party shall use Commercially Reasonable Efforts to Commercialize the Product in its Party Major Market(s) in accordance with and to the extent provided in the Combined Major Market Commercialization Plan, the applicable Party Major Market Commercialization Plan, and otherwise in accordance with this Agreement.
- **4.3.4** <u>Sales Efforts Reporting for the Party Major Market(s)</u>. Within [\*] after the end of each Year beginning in the Year in which the first Regulatory Approval of the Product in a Party's Party Major Market(s) is obtained, each Party shall provide a high-level report to the JCC summarizing its selling efforts for the Product where the Product receives a primary or secondary ranking in its Party Major Market(s).
- 4.3.5 Packaging and Labeling; Booking of Sales; Distribution in the Major Markets. In its Party Major Market(s), the Selling Party (a) will hold title to the Product inventories until such inventory is sold to customers, (b) shall effect all sales of Product and shall be responsible for invoicing all sales of Product and shall book all sales of Product for its own account, and (c) shall be responsible for all Packaging and Labeling and Sales and Distribution activities for the Product. Notwithstanding the foregoing, to the extent not prohibited by Applicable Law and subject to approval by the applicable Regulatory Authorities, unless the Parties otherwise agree by mutual Party Written Consent, all product labels for the Product worldwide shall include, in equal prominence, the [\*].

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- **4.4** Commercialization in the Royalty Territory. Following the receipt of relevant Regulatory Approvals in relevant country(ies), SGI shall use Commercially Reasonable Efforts to Commercialize the Product in [\*], as determined by SGI in its reasonable discretion consistent with its obligation to use Commercially Reasonable Efforts to Commercialize the Product in the Royalty Territory, in accordance with the terms and conditions of this Agreement, and except as otherwise provided in this Agreement shall be solely responsible for all costs and expenses incurred by or on behalf of SGI or any of its Affiliates for Commercializing the Product in the Royalty Territory or any portion thereof. For the avoidance of doubt, SGI may satisfy its obligations under this Section 4.4 by using Commercially Reasonable Efforts to enter into (or entering into) one or more Commercial Sublicenses with respect to one or more countries in the Royalty Territory.
- 4.5 Recalls and Withdrawals. The initiation and implementation of a Product distribution hold, recall, clinical hold, market withdrawal, or similar action in the Territory will be determined in accordance with the relevant clinical or commercial quality agreement agreed to by the Parties in accordance with Section 6.3 (including the process for consultation and, if possible, reaching consensus set forth therein); provided, that the Lead Regulatory Party shall have final decision-making authority, after consultation with the other Party with respect to the initiation and conduct of any such hold, recall, withdrawal, or similar action in a particular country if there is a dispute between the Parties with respect thereto (unless there is a mandatory hold, recall, withdrawal, or similar action by the Regulatory Authorities, which shall supersede any decision of the Lead Regulatory Party to the contrary). The costs of implementing any such hold, recall, withdrawal, or action in accordance with this Section 4.5 in the Major Markets shall constitute Commercialization Costs except to the extent that such hold, recall, withdrawal, or action is (a) attributable to (i) a breach by a Party or its Affiliates of this Agreement or (ii) the gross negligence, recklessness or willful misconduct of a Party or its Affiliates, or (b) caused by or results directly from a material uncured breach by a Party or its Affiliates of any agreement with a Third Party CMO engaged by such Party or its Affiliate for the Manufacture of Product if such material breach is acknowledged by such Party in writing, results from a failure by the Manufacturing Party to make any undisputed payment when due (after giving effect to any available cure period) or is finally determined by a court or arbitrator of competent jurisdiction; *provided*, that the foregoing clause (b) shall not apply to any such material breach that is caused by or results directly from an act or omission of a Third Party including any other Third Party CMO that Manufactures the Product on the Party's behalf. Any such costs not included in Commercialization Costs pursuant to the preceding sentence shall be borne solely by the applicable Party.

## **4.6** <u>Development Activities.</u>

- **4.6.1** <u>In General</u>. Except as otherwise expressly provided in this Agreement, including <u>Sections 2.3</u>, <u>4.6.2</u> and <u>8.1.2</u>, Development of the Product in the Territory following the Effective Date will continue to be conducted in accordance with the terms and conditions of the Collaboration Agreement.
  - **4.6.2** <u>Clinical Trials</u>. Notwithstanding anything to the contrary contained in the

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Collaboration Agreement or the Joint Development Plan as of the Effective Date, following the Effective Date: (a) Genmab shall be the sponsor of and solely conduct and be responsible for the performance of (i) the Clinical Trials known as [\*], (ii) to the extent such studies are included in the Global Development Plan, any Phase III-B Studies or Phase IV Studies conducted in the Genmab Major Market, (iii) any Genmab Party Combination Studies to be conducted by or on behalf of Genmab, to the extent such studies are included in the Global Development Plan (such Global Development Plan to also set forth the details regarding Clinical Supply and data sharing with respect to such Genmab Party Combination Studies), and (iv) any Genmab [\*] Approval Trial initiated by Genmab in accordance with Section 0; and (b) SGI shall be the sponsor of and solely conduct and be responsible for the performance of any other Clinical Trials of the Product which are not specified in clause (a) above, including (1) the Clinical Trials known as [\*], (2) any other Clinical Trials for the Product to be conducted for [\*], (3) any Phase III-B or Phase IV Studies, (4) any SGI Party Combination Studies to be conducted by or on behalf of SGI, to the extent such studies are included in the Global Development Plan (such Global Development Plan to also set forth the details regarding Clinical Supply and data sharing with respect to such SGI Party Combination Studies), and (5) any Clinical Trial regarding the Product and any other product owned or otherwise controlled by a Third Party, to the extent such studies are included in the Global Development Plan. For clarity, the foregoing is intended to establish which Party will have operational control over relevant Clinical Trials following the Effective Date, but it is not intended to prevent the other Party from performing Medical Affairs Activities, including through outreach and contacts with Clinical Trial sites, in its Party Major Market(s) to the extent otherwise permitted under this Agreement.

Development in [\*]. It is the expectation of the Parties that Clinical Trials for the Product conducted by SGI as sponsor in accordance with Section 4.6.2 will include an adequate patient population from [\*] to support Regulatory Approval of the Product in [\*] for the Disease(s) for which such Clinical Trials are intended to treat. However, to the extent that it is not reasonably practicable for such Clinical Trials to include an adequate patient population from [\*] to support such Regulatory Approval of the Product in [\*], the Parties, acting through the JDC, will promptly amend the Global Development Plan to add such Clinical Trial(s) to be conducted in [\*] with an adequate patient population from [\*] to support such Regulatory Approval in [\*] (any such Clinical Trial, a "Genmab [\*] Approval Trial"), and Genmab shall be the sponsor of and solely conduct and be responsible for the performance of any such Genmab [\*] Approval Trial. For the avoidance of doubt, the FTE Costs of Genmab's personnel and Out of Pocket Costs incurred by Genmab in connection with the planning and conduct of any Genmab [\*] Approval Trial, including Manufacturing Costs for Clinical Supply and any comparator or placebo therefor, shall be considered Development Costs hereunder.

**4.6.3** Development in the Royalty Territory. SGI shall use Commercially Reasonable Efforts to Develop the Product in the Royalty Territory, as determined by SGI in its reasonable discretion consistent with its obligation to use Commercially Reasonable Efforts to Develop the Product in the Royalty Territory, in accordance with and to the extent provided from time to time in the mutually agreed Global Development Plan (including any amendments or modifications to the Global Development Plan with respect to the Royalty Territory proposed by SGI consistent with its obligation to use Commercially Reasonable Efforts). For clarity, if Genmab or its representatives on any Committee refuse to approve any such amendment or modification to the Global Development Plan with respect to the Royalty Territory, SGI shall not be deemed to

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have failed to use [\*].

**4.6.4** <u>Development Costs</u>. Development Costs incurred by the Parties in connection with Development activities conducted for the Product under this Agreement (including [\*]) in accordance with the Global Development Plan shall be shared as Net Profit/Net Loss in accordance with <u>Section 5.1</u> and the other applicable terms and conditions of this Agreement. For clarity, any Development activities conducted by or on behalf of SGI or its Affiliates or their Sublicensees for countries in the Royalty Territory that are not included in the Global Development Plan shall be at SGI's sole cost and expense, and shall not be shared as Net Profit/Net Loss hereunder.

## **4.7** <u>Subcontracting and Sublicensing.</u>

- Subcontracting. Each Party may perform some or all of its obligations (a) under the Global Development Plan (including the Global Regulatory Plan), Global Manufacturing Plan and Party Major Market Commercialization Plan or (b) otherwise under this Agreement for the Product in its Party Major Market(s) (or with respect to Genmab and the Genmab US Activities, in the United States subject to ARTICLE 3), in each case ((a) and (b)), solely through one or more Approved Subcontractors or as otherwise approved by the JSC; provided, that (i) none of the rights of the other Party shall be diminished or otherwise adversely affected as a result of such subcontracting, (ii) nothing in this <u>Section 4.7.1</u> shall limit a requirement to obtain Party Written Consent or Joint Committee Consent for Third Party Manufacturing under ARTICLE 6, (iii) each subcontractor shall undertake in writing obligations of confidentiality and non-use regarding each Party's Confidential Information which are substantially the same as those undertaken by the Parties hereunder, and (iv) the subcontracting Party shall be responsible for the performance by such subcontractor of such Party's obligations hereunder. For clarity, the Parties and their Affiliates may enter into arrangements with (X) nationally recognized shipping or transportation companies such as United Parcel Service or FedEx or (Y) with contract research organizations with respect to non-clinical Development, in each case of (X) and (Y), with respect to the Product or their obligations under this Agreement without the prior Committee approval and, solely with respect to (X), such arrangements shall be excluded from the requirements of clause (ii) above. Notwithstanding the foregoing or anything to the contrary contained in this Agreement or the Collaboration Agreement, SGI may engage subcontractors to perform Development, Manufacturing, or Commercialization activities with respect to the Product in the Royalty Territory or outside the Royalty Territory solely to support Development or Commercialization of the Product in the Royalty Territory without the prior written consent of Genmab or any Committee, *provided* that subsections (i)-(iii) above shall continue to apply.
- **4.7.2** <u>Sublicensing.</u> This <u>Section 4.7.2</u> supersedes Section 5.11 of the Collaboration Agreement with respect to the grant by either Party of a Commercial Sublicense for the Product to a Third Party. In addition, to the extent any sublicense permitted under this Agreement would require the grant of a sublicense under the Collaboration Agreement with respect to the Product, the Parties agree to grant that sublicense with respect to the Product notwithstanding anything to the contrary in the Collaboration Agreement.
  - (a) <u>In General</u>. Except as expressly provided in this <u>Section 4.7.2</u>,

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neither Party shall grant any [\*] with respect to their [\*] to any Third Party without the consent of the JSC, such consent not to be unreasonably withheld, delayed, or conditioned.

- **(b)** <u>Service Providers.</u> Subject to <u>Section 4.7.2(a)</u>, each Party may sublicense its rights and obligations under this Agreement and the Collaboration Agreement to a subcontractor permitted under <u>Section 4.7.1</u> to the extent necessary to enable such subcontractor to perform its obligations to the subcontracting Party.
- (c) <u>Third Party Sublicensing</u>. With respect to the grant by a Party or its Affiliate to a Third Party sublicensee that includes the right to Commercialize the Product, but not including any wholesaler, distributor, or the like (such sublicensee, a "<u>Sublicensee</u>," and such sublicense, a "<u>Commercial Sublicensee</u>"):
- (i) In the [\*] Markets. If a Party desires to grant a Commercial Sublicense in countries or territories that include one or more of its Party [\*] Market(s), such Party shall notify the other Party in writing thereof. Thereafter, the Parties, through the JSC, shall discuss the strategy, timing, and other considerations relating to finding an appropriate Sublicensee for such [\*] Market Sublicense. If the JSC agrees to pursue a Sublicensee to Commercialize Product in such [\*] Market, then (i) each Party shall take the [\*] Market Sublicense that includes solely the Party [\*] Market(s) of such Party, and (ii) if such [\*] Market Sublicense would involve the grant of rights in or for the Party [\*] Market(s) of both Parties, the JSC shall determine which Party [\*]. The [\*] Party shall provide the other Party [\*] without the approval of the JSC, such approval not to be unreasonably withheld, delayed, or conditioned.
- (ii) In the Royalty Territory. SGI may grant a Commercial Sublicense in or for countries or territories solely within the Royalty Territory in its sole discretion; *provided*, that, without limiting the foregoing, SGI will first notify Genmab and upon a written request by Genmab within [\*] of SGI's notice, SGI shall reasonably consider [\*]. For the avoidance of doubt, (A) Product sales by any such Sublicensee in the Royalty Territory shall be considered Net Sales to the extent provided in the definition of "Net Sales" hereunder, (B) Product sales to any Third Party distributor, wholesaler, or the like in or for the Royalty Territory shall be considered Net Sales to the extent provided in the definition of "Net Sales" hereunder, and (C) any other consideration paid to SGI or any of its Affiliates by or on behalf of any such Sublicensee or distributer, wholesaler, or the like shall be retained by SGI and shall not be considered "Sublicensing Revenue" hereunder.
- **(d)** [\*] <u>Sublicensing.</u> Without limiting subsection (c)(i) above, the Parties acknowledge that prior to the Effective Date, [\*] initiated a business development process with respect to the potential out-license of rights to Commercialize the Product in [\*] (the "<u>Process</u>"). Subject to subsection (c)(i) above, [\*] shall transition the Process to [\*] following the Effective Date, and [\*] may continue the Process or otherwise pursue a Commercial Sublicense with respect to [\*] in accordance with subsection (c)(i) above.

## ARTICLE 5 FINANCIAL TERMS

The Parties shall make or cause to be made the payments provided for in this <u>ARTICLE 5</u>.

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For clarity, this <u>ARTICLE 5</u> supersedes Sections 11.4, 11.5, 11.6, and Article 12 of the Collaboration Agreement with respect to activities conducted after the Effective Date with respect to the Product.

- **5.1** <u>Profit Sharing in the Major Markets</u>. Following the Effective Date, the terms and conditions of this <u>Section 5.1</u> shall govern the rights and obligations of Genmab and SGI with respect to Net Profit/Net Loss relating to the Product.
- **5.1.1** Share of Net Profits/Net Losses. Subject to the terms of this Agreement and Section 5.10 of the Collaboration Agreement, for so long as Product is being sold in the Major Markets or Sublicensing Revenue is being generated, Genmab and SGI shall share all Net Profit/Net Loss (as applicable) for the Product on the basis of fifty percent (50%) to SGI and fifty percent (50%) to Genmab.

# **5.1.2** <u>Calculation and Payment.</u>

- (a) Within [\*] days after the end of each Quarter beginning with the first Quarter in which either Development Costs or Allowable Expenses are incurred, each Party shall report to the JFT its Net Sales and Sublicensing Revenue in the Major Markets, as well as its Allowable Expenses and Development Costs. Each such report shall, as applicable, specify in reasonable detail all deductions allowed in the calculation of such Net Sales, documentation supporting its receipts of such Sublicensing Revenue, and all expenses or costs included in Allowable Expenses or Development Costs, and, if requested by Genmab or SGI, any invoices or other supporting documentation for any payments to a Third Party that constitute Allowable Expenses or Development Costs and that individually exceed [\*] or with respect to which documentation is otherwise reasonably requested shall be promptly provided. In addition, each such report shall specify the amount of gross sales of Product for the Quarter and the amount offset from gross sales to Net Sales by category for the Quarter. Within [\*] Business Days after receipt of such reports, the JFT shall confer and agree in writing on a consolidated financial statement setting forth the Net Profit/Net Loss for such Quarter for the Product and calculating each Party's share of such Net Profit/Net Loss.
- (b) Within [\*] Business Days after the Parties (through the JFT) have reconciled the reports delivered under Section 5.1.2(a) for each Quarter, the Party who will receive payment shall issue to the other Party an invoice for the agreed amount and the other Party shall, within [\*] Business Days of such invoice, make a payment to SGI or Genmab, as applicable, so that each of Genmab and SGI has been compensated for its respective share or has borne its respective share of such Net Profit/Net Loss, as applicable, after giving effect to the (i) Net Sales invoiced and Sublicensing Revenue received for the Major Markets as well as Allowable Expenses and Development Costs incurred by SGI, and (ii) Net Sales invoiced and Sublicensing Revenue received for the Major Markets, as well as Allowable Expenses and Development Costs incurred by Genmab, to effect the intent of Section 5.1.1; provided, however, that in the event of any disagreement with respect to the calculation of such payment, any undisputed portion of such payment shall be paid in accordance with the foregoing timetable and the remaining, disputed portion shall be paid within [\*] Business Days after the date on which Genmab and SGI, using good faith efforts, resolve the dispute or such dispute is resolved pursuant to a dispute resolution mechanism under this Agreement.

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- (c) In addition, for planning purposes, each Party shall report to the other Party and the JFT within [\*] Business Days after the end of each calendar month following the first Launch of the Product in its Party Major Market(s) its estimated Net Sales (including the estimated amount of gross sales of Product by stock keeping units of Product) in its Party Major Market(s) in such month and its estimated Allowable Expenses in such month. Further, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit each Party to close its books periodically in a timely manner.
- (d) If either Party intends to include a Net Sales forecast or a Net Profit/Net Loss forecast in any public filings or public statements in connection with its required financial reporting to any Securities Exchange, the Parties agree to cooperate in good faith to prepare Net Sales or Net Profit/Net Loss forecasts reasonably in advance of such filing or public statement; *provided*, that if the Parties are unable to agree to such forecasts in advance of such filing or public statement, the filing Party shall be permitted to use its good faith Net Sales or Net Profit/Net Loss forecasts in such filing or public statement.
- (e) For the avoidance of doubt, no cost or expense shall be counted more than once in calculating Allowable Expenses or Development Costs, even if such cost or expense falls into more than one of the cost categories that comprise Allowable Expenses or Development Costs. For purposes of determining Allowable Expenses, Development Costs and Net Profit/Net Loss, each Party shall be required to record for relevant employees aggregate FTE hours worked or FTE hours worked on activities related to the Product (subject to Section 1.49) and all such allowed FTE Costs shall be charged based on the percentage of time allocated to the Product and activities under this Agreement (or as otherwise set forth in Section 1.49). Out of Pocket Costs will be charged based on actual expenses incurred or accrued.
- **5.1.3** <u>Consistency with Accounting Treatment</u>. All calculations of Net Profit/Net Loss hereunder shall be made in accordance with Collaboration Accounting Standards, including the provisions thereof regarding expense recognition, as applied by Genmab and SGI consistently with their application in their respective external financial reporting.

## **5.1.4** <u>Integrity of Profit Sharing in the Major Markets.</u>

- (a) The Parties recognize that in certain regions, restrictions on cross- border sales of the Product are not permitted, and that in such regions (*e.g.*, within the EU), sales of units of the Product intended to be sold in a Major Market and therefore subject to payment obligations under Section 5.1 may instead be sold in a country that is in the Royalty Territory instead, and initially included in amounts subject to royalty obligations under Section 5.2. In such case, the Parties have agreed to perform an annual assessment of whether their intended allocation of economic benefit as set forth in Sections 5.1 and 5.2 has been effected and, if not, to make reconciling payments between the Parties to effectuate their intent as set forth in Sections 5.1 and 5.2, pursuant to the mechanism set forth in this Section 5.1.4.
- **(b)** Within [\*] days after the end of the Quarter in which the first Launch of the Product in a Major Market occurs, and within [\*] days after the end of each Quarter

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thereafter, the Parties, through the JCC and in coordination with the JFT, shall review for such Quarter that most recently ended ("Relevant Review Period") the following information: (A) the total amount of Net Sales allocated to the Major Markets for the purpose of calculating the Net Profit/Net Loss for the Major Markets in accordance with this Section 5.1, (B) the total amount of Net Sales allocated to the Royalty Territory for the purpose of calculating the total royalties due by SGI to Genmab in accordance with Section 5.1.4, (C) the estimated amount of total prescriptions issued for the Product in the Major Markets, in accordance with data obtained from IQVIA or another source mutually acceptable to the Parties, and (D) the estimated amount of total prescriptions issued for the Product in the Royalty Territory, in accordance with data obtained from IQVIA or another source mutually acceptable to the Parties, in each case of (A)-(D), during the Relevant Review Period. To the extent that the fraction A/B is less than or greater than the fraction C/D, then the JCC, in coordination with the JFT shall determine reconciling payments to be made between the Parties with respect to the Relevant Review Period as necessary to effectuate their intended allocation of the economic benefit as set forth in such Sections (a "Reconciling Payment Determination"). Any such reconciling payments shall be made within [\*] days after the JFT has made a Reconciling Payment Determination.

## 5.2 Royalty Territory.

**5.2.1** <u>Royalty Payments.</u> Subject to <u>Sections 5.2.2</u> and <u>5.2.3</u>, during each Quarter in which such Net Sales are received, SGI shall pay Genmab a running royalty on aggregate annual Net Sales of the Product in the Royalty Territory by SGI, its Affiliates and their Sublicensees at the following percentages as set forth in the table below:

Portion of aggregate annual Net Sales of the Product in the Royalty Territory by SGI, its Affiliates, and their Sublicensees	Percentage of such Net Sales to be paid as a running royalty:
[*]	[*]
[*]	[*]
[*]	[*]

5.2.2 <u>Biosimilar Step-Down.</u> If, on a country-by-country basis within the Royalty Territory, one or more Biosimilar Products in respect of the Product are sold in such country, and if sales of all Biosimilar Products in respect of the Product combined in such country during any [\*] are greater than [\*] (on a unit basis) of the combined sales of all such Biosimilar Products and the Product together (on a unit basis) in such country (the "<u>Trigger Condition</u>"), then the royalties payable with respect to Net Sales of the Product pursuant to <u>Section 5.2.1</u> in such country starting with [\*] giving rise to the Trigger Condition shall be reduced to [\*] of the royalties otherwise payable pursuant to <u>Section 5.2.1</u>; *provided*, that if the Trigger Condition ceases to apply in a future Quarter, after royalties are subject to reduction pursuant to this <u>Section 5.2.2</u>, such reduction in royalties shall cease to apply effective as of the subsequent Quarter unless and until the Trigger Condition occurs again for the Product in such country.

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- 5.2.3 Royalty Term. SGI's obligation to pay royalties under this Section 5.2 with respect to the Product in each country in the Royalty Territory will commence upon Launch of the Product in such country and will continue until the later of (i) expiration of the last-to-expire [\*] of the [\*] covering Program Inventions claiming or covering the Product in such country or (ii) [\*] after such Launch of the Product in such country (such period, the "Royalty Term"); provided, however, that if the Product is royalty-bearing in a given country only pursuant to clause (ii) above, then the each royalty rate set forth in Section 5.2.1 shall be reduced by [\*] for such country for the remainder of the Royalty Term and; provided, further, that in no event shall the royalty rates set forth in Section 5.2.1 be reduced pursuant to Section 5.2.2 and this Section 5.2.3 by more than [\*], in the aggregate.
- **5.2.4** Royalty Payments and Reports. Within [\*] days after the end of each March, June, September and December during which royalties under this Section 5.2 are due, SGI shall deliver to Genmab a report setting forth on a country-by-country basis the unit volume and amount of gross sales of Product sold by SGI its Affiliates and their Sublicensees in the Royalty Territory during the applicable Quarter, a calculation of such Net Sales in the Royalty Territory showing the aggregate deductions from gross sales provided for in the definition of Net Sales during such Quarter, and a calculation of the royalty payment due for such Quarter. All royalty amounts payable to Genmab pursuant to this Section 5.2.4 shall be paid to Genmab in Dollars in connection with the delivery of such report, but not later than [\*] days after the end of each Quarter.

## **5.3** <u>Taxes</u>.

- **5.3.1** Taxes on Income. Except as otherwise provided in this Section 5.3 or Schedule 5.3.4, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly under this Agreement.
- 5.3.2 Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding, Indirect Taxes, or similar obligations in respect of Net Profit, royalties and other payments made by one Party to the other under this Agreement. Without limiting the generality of the foregoing, to the extent that a Party (or its assignee) (the "Paying Party") is required by Applicable Law to deduct and withhold taxes on any payment due to the other Party (or its assignee) (the "Payee Party") under this Agreement, the Paying Party shall provide [\*] Business Days' notice of such intention to withhold to the Payee Party, and the Payee Party shall provide the Paying Party any tax forms and other information that may be reasonably necessary in order not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. The Payee Party shall provide any such tax forms to the Paying Party at least [\*] Business Days prior to the due date for any payment for which the Payee Party desires that the Paying Party apply a reduced withholding rate.

All payments payable under this Agreement are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments made under this Agreement, the Paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the Payee Party in respect of those payments.

Each Party shall provide the other with reasonable assistance to enable the recovery,

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as permitted by Applicable Law, of withholding taxes, Indirect Taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or Indirect Tax. For clarity, if such withholding taxes, Indirect Taxes, or similar obligations have been shared equally by the Parties as an Allowable Expense, the Parties shall share equally in the amount of such recovery.

#### **5.3.3** Payment of Tax.

(a) To the extent that a Paying Party is required by Applicable Law to deduct and withhold taxes on any payment due to the Payee Party under this Agreement or allocation of Net Profits/Net Losses under this Agreement, such Paying Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the Payee Party evidence of such withholding in the form customarily provided by the applicable Governmental Authority to enable the Payee Party to claim such payment of taxes. Any taxes that are so deducted and withheld shall be treated as paid to the Payee Party hereunder. If the Paying Party failed to deduct or withhold tax required by Applicable Law, the Payee Party shall [\*]. In the event that a liability for withholding taxes is imposed or asserted by a Governmental Authority upon the Paying Party in respect of a failure to withhold such taxes from or in respect of any amount payable to a Payee Party under this Agreement (a "Withholding Tax Claim"), (1) the Paying Party shall notify the Payee Party promptly upon the receipt of any such Withholding Tax Claim from a Governmental Authority which might give rise to an indemnification under this Section 5.3.3 (although the Paying Party's delay in promptly notifying the Payee Party shall only reduce the Payee Party's liability to indemnify the Paying Party to the extent that the Payee Party is actually prejudiced by such delay); (2) the Payee Party shall be entitled to participate, at its own expense, and with counsel of its choosing, in the defense of any such Withholding Tax Claim which may give rise to liability under this Section 5.3.3(a); (3) the Paying Party may not settle the Withholding Tax Claim with a Governmental Authority, to the extent such settlement would create a liability for the Payee Party under this <u>Section 5.3.3(a)</u>, without the prior written consent of the Payee Party, which consent shall not be unreasonably withheld, conditioned or delayed; and (4) the Payee Party shall indemnify the Paying Party for any reasonable out-of-pocket expenses incurred by the Paying Party in the defense of the Withholding Tax Claim; provided, further, that the foregoing indemnification obligation shall not apply to the extent that if the Paying Party had withheld such taxes, it would have been required to increase such amount payable under <u>Section 5.3.3(b)</u>.

(b) Notwithstanding the foregoing, if (a) any Party redomiciles or assigns its rights or obligations under this Agreement, (b) as a result of such redomiciliation or assignment, such Party (or its assignee) is required by Applicable Law to withhold taxes, or such redomiciliation or assignment results in the imposition of Indirect Taxes that were not otherwise applicable, from or in respect of any amount payable from such Party to the other Party under this Agreement, and (c) such withholding taxes or Indirect Taxes exceed the amount of withholding taxes or Indirect Taxes that would have been applicable had such redomiciliation or assignment not occurred, then any such amount payable shall be increased to take into account such withholding taxes or Indirect Taxes as may be necessary so that, after making all required withholdings (including withholdings on the additional amounts payable) and/or paying such Indirect Taxes, as the case may be, the Payee Party (or its assignee) receives an amount equal to the sum it would have received had no such increased withholding been made and no such Indirect

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Taxes had been imposed. The obligation to pay additional amounts pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding tax or Indirect Taxes (i) would not have been imposed but for the assignment by the Payee Party of its rights or obligations under this Agreement or the redomiciliation of such Payee Party outside of the United States, to the extent such assignment or redomiciliation occurs after the redomiciliation or assignment by the Paying Party described in the first sentence of this Section 5.3.3(b) or (ii) are attributable to the failure by the Payee Party to comply with the requirements of Section 5.3.3(c).

- (c) Each Party has provided a properly completed and duly executed IRS Form W-9 or applicable Form W-8 to the other Parties. Each Party and any other recipient of payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by such other Parties or as required or permitted by Applicable Law, such properly completed and duly executed documentation (for example, IRS Forms W-8 or W-9) as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes.
- 5.3.4 Partnership Tax Treatment. Each Party understands, acknowledges and agrees that to the extent the Parties are sharing Net Profits/Net Losses pursuant to Section 5.1.1 with respect to the Development and Commercialization of the Product then a partnership for United States income tax purposes is formed between the Parties (the "Tax Partnership"). The Parties further agree and acknowledge that, for U.S. federal income tax purposes, the Tax Partnership commenced upon the effective date of the Joint Commercialization Agreement (the "Tax Partnership Formation Date"). The Parties intend that for U.S. federal (and applicable state) income tax purposes, each of Genmab and SGI shall be treated as having contributed property of equal value to the Tax Partnership on the Tax Partnership Formation Date (such value to be determined by mutual agreement of the Parties) in a transaction intended to qualify for non-recognition treatment under Section 721(a) of the U.S. Internal Revenue Code of 1986, as amended (the "Tax Code"). The Parties further acknowledge and agree that the Royalty Payments provided for under <u>Section 5.2</u> shall not be treated as contributions to or distributions from the Tax Partnership, but shall be treated by the Parties as payments made outside of the Tax Partnership (by SGI to Genmab not in their capacity as Partners in the Tax Partnership). The Tax Partnership shall be governed and operated in accordance with the rights and obligations set forth in Schedule 5.3.4. The Parties further acknowledge that the arrangements described in this Agreement (including Schedule 5.3.4) shall be treated by the Parties as a partnership solely for U.S. federal (and applicable state) income tax purposes and is not intended to constitute a partnership for any non-tax purpose or for tax purposes under the laws of any non-U.S. jurisdiction. The Parties agree to cooperate in good faith to take such reasonable actions and execute such documents as reasonably necessary to support the tax position set forth in this Section 5.3.4 and **Schedule 5.3.4**.
- 5.3.5 <u>Effectively Connected Income</u>. The Parties shall coordinate and cooperate reasonably and in good faith to review the anticipated tax consequences associated with the Development and Commercialization activities undertaken by the Parties (and their respective Affiliates) pursuant to this Agreement and structure such activities in a manner to minimize, to the extent permitted by Applicable Law, the income generated from activities that constitutes income effectively connected with a trade or business within the United States (within the meaning of Section 864 of the Tax Code) ("<u>ECI</u>") or profits attributable to a permanent establishment or other

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similar taxable presence of either Party in any jurisdiction outside of the United States. Each Party, upon request, shall provide information to the other Party about the location and structure of its Development and Commercialization activities reasonably in connection with the foregoing review. The determination of the structure of Development and Commercialization activities for the foregoing purposes shall be made by the JCC; *provided*, *however*, that neither Party shall be required to undertake actions that could reasonably be expected to result in adverse tax or business consequences to such Party (including any liability for taxes that are not indemnified by the other Party under Section 5.3.3) or that would cause such Party to incur material out-of-pocket costs (other than any out-of-pocket costs that the other Party agrees to reimburse).

- **5.4** <u>Currency</u>. All payments hereunder will be in Dollars in immediately available funds and will be made by wire transfer from a United States bank located in the United States to such bank account as payee may designate in writing from time to time.
- **5.5** <u>Foreign Exchange</u>. The amounts accruing in a currency other than Dollars will be converted to Dollars using an exchange rate equal to, unless otherwise agreed by the JFT, the arithmetic average of the U.S. daily closing rates published by Reuters during the applicable Quarter for which payments are being made or applicable costs are accrued. The conversion calculations will be provided in any statement reporting converted amounts.
- **5.6** <u>Late Payments</u>. Any undisputed payments or portions thereof due hereunder which are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of (a) the prime rate as published in The Wall Street Journal, Eastern Edition, under the heading "Money Rates," on the first date of each Quarter in which such payments are overdue, plus [\*] or (b) the maximum rate permitted by Applicable Law, in each case ((a) and (b)), calculated on the number of days such payment is delinquent, compounded monthly using a three hundred sixty-five (365)-day year.
- 5.7 Financial Records; Audits. Each Party shall maintain, and require its Affiliates to maintain, complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of any calculations by the other Party or any payments due by the other Party under this Agreement, including (a) amounts to be included in the calculation of Allowable Expenses or other amounts to be reimbursed or shared pursuant to this Agreement, (b) Net Sales, (a) royalty payments for purposes of determining any under- or over-payment of royalties, (b) Manufacturing Costs, Commercial Packaging and Labeling Costs, Commercialization Costs, and Medical Affairs Costs, (e) amounts payable under any supply agreement with respect to the Product to which the Parties or their Affiliates are party, and (f) other compensation or reimbursement payable under this Agreement. Upon reasonable prior notice, such records for any Year(s) ending not more than [\*] prior to the date of such request shall be open during regular business hours for examination at the auditing Party's expense, and not more often than once each [\*] period, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial statements or reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party to the other Party pursuant to this Agreement or any supply agreement with respect to the Product to which the Parties or their Affiliates are party. Such accountant shall be provided access to the audited Party's data for the purpose of verifying, without limitation, the audited Party's

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determination of the number of FTEs (if applicable), and calculation of such other information included in the calculation for Manufacturing Costs, Commercial Packaging and Labeling Costs, Commercialization Costs, and Medical Affairs Costs actually incurred by the audited Party for the Product. Any such auditor shall not disclose the audited Party's information to the auditing Party, except to the extent that such disclosure is necessary to report on the accuracy of the financial reports furnished by the audited Party or the amount of payments due by the audited Party under this Agreement. Any amounts shown to be owed but unpaid, or overpaid, shall be paid or refunded (as the case may be) within [\*] days after the accountant's report, unless such report is challenged in good faith by the audited Party, in which case any undisputed portion shall be paid within [\*] days after resolution of the dispute, and interest shall not accrue with respect to the disputed portion during the period of time the dispute is being resolved. The auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party that resulted from a discrepancy in a report that the audited Party provided to the other Party during the applicable audit period, which underpayment or overpayment was more than [\*], in which case the audited Party shall bear the Out of Pocket Costs of such audit.

#### **5.8** Third Party License Agreements.

- **5.8.1** Each Party shall promptly notify the other Party via discussion at the JSC or any Committee charged with oversight for intellectual property matters, or between the Alliance Managers, if either Party believes that Patent or other intellectual property rights controlled by a Third Party (but not already Controlled by a Party) may be necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Product in or for one or more Major Markets and such notifying Party proposes that a Party should enter into a Third Party License Agreement therefor for one or more Major Markets.
- **5.8.2** The Parties, through the JSC, shall discuss whether or not to negotiate the terms of such Third Party License Agreement for one or more Major Markets. The determination of whether to pursue the negotiation of any such Third Party License Agreement for one or more Major Markets must be made by the JSC.
- 5.8.3 If the JSC decides to pursue the negotiation of a Third Party License Agreement for one or more Major Markets, the JSC shall also decide which Party or whether the Parties jointly shall take the lead on negotiating the terms of such Third Party License Agreement (the "Lead Negotiating Party."); provided, that the presumption shall be that (a) SGI shall be the Lead Negotiating Party for a Third Party License Agreement for one or more SGI Major Markets, unless such Third Party License Agreement relates primarily to the Genmab Technology rather than the Product, in which case Genmab shall be the Lead Negotiating Party, and (b) Genmab shall be the Lead Negotiation Party for a Third Party License Agreement for the Genmab Major Market, unless such Third Party License Agreement relates primarily to the SGI Technology rather than the Product, in which case SGI shall be the Lead Negotiating Party. If the Lead Negotiating Party elects not to or to cease taking the lead on negotiating the terms of a Third Party License Agreement, it shall promptly notify the other Party and transition the negotiation thereof to the other Party. For the avoidance of doubt, the JSC may decide to discontinue any such negotiation or decide that neither Party shall enter into any Third Party License Agreement so negotiated.

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- **5.8.4** In connection with any negotiation of a Third Party License Agreement for one or more Major Markets: (a) the terms of any such license shall permit the Party obtaining such Third Party License Agreement to grant to the other Party a sublicense thereunder to practice the licensed rights thereunder; (b) the Parties, in consultation through the JSC, shall cooperate in negotiating the terms of such Third Party License Agreement with such Third Party as reasonably necessary to enable such other Party to exercise its rights under this Agreement; and (c) the Lead Negotiating Party for such Third Party License Agreement shall consult with the other Party through the JSC prior to making any material proposal regarding, or otherwise agreeing to, the terms of any such license. Additionally, the Parties shall negotiate and structure such Third Party License Agreement in a fair and equitable manner, taking into consideration the manner in which such license rights are to be used, and, unless otherwise mutually agreed by the Parties, shall not structure any such arrangement with the purpose or effect of shifting to one Party or the other the amount of Payments to Third Parties for which either Party will be responsible (if any) pursuant to this Agreement.
- **5.8.5** The terms of a Third Party License Agreement for one or more Major Markets, and any amendment thereto, must be approved by the JSC prior to execution thereof.
- 5.8.6 SGI shall promptly notify Genmab via discussion at the JSC or any Committee charged with oversight for intellectual property matters, or between the Alliance Managers, if SGI believes that Patent or other intellectual property rights controlled by a Third Party (but not already Controlled by a Party) may be necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Product in or for one or more countries in the Royalty Territory. Prior to execution, SGI will discuss with Genmab any proposed Third Party License Agreement for one or more countries in the Royalty Territory and SGI will consider any Genmab input thereon in good faith, but, for the avoidance of doubt, SGI may enter into one or more Third Party License Agreements for one or more countries in the Royalty Territory in its sole discretion; *provided*, that neither Party is aware of equivalent Third Party intellectual property rights that exist outside of the Royalty Territory which may be necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Product in or for one or more Major Markets. In case such equivalent Third Party intellectual property rights exist outside of the Royalty Territory, any Third Party License Agreement with respect to the Royalty Territory and Major Market(s) shall be handled in accordance with Sections 5.8.1 to 5.8.5.

#### **5.9** Payment to Third Parties.

**5.9.1** All Payments to Third Parties (i) (A) if triggered by Development activities directed towards obtaining Regulatory Approval of the Product in the Major Markets, shall be included as Development Costs for the Product, and (B) if triggered by Development activities directed towards obtaining Regulatory Approval of a Product in the Royalty Territory, shall be borne solely by SGI and (ii) (A) if triggered by Commercialization of a Product in a country in the Major Markets, shall be treated as Allowable Expenses for the Product, and (B) if triggered by Commercialization of a Product in a country or territory in the Royalty Territory, shall be borne solely by SGI. If a given Payment to Third Parties is not triggered by territory-dependent activities (e.g., an upfront payment), then a reasonable portion of such Payment to Third Parties shall, (X) to the extent directly attributable or reasonably allocable to the Major Markets, be treated as an

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Allowable Expense for the Product and (Y) to the extent directly attributable or reasonably allocable to the Royalty Territory, be borne solely by SGI.

**5.9.2** Genmab represents and warrants to SGI, as of the Effective Date, that the copies of the [\*] Agreement and the [\*] Agreement provided to SGI prior to the Effective Date are true, complete (except for redactions relating to products other than the Product), and correct in all respects, and that neither Genmab nor its Affiliates are party to any other agreement or arrangement, whether written or oral, that either would or would be reasonably likely to result in Payments to Third Parties following the Effective Date. SGI warrants to Genmab, as of the Effective Date, that neither SGI nor its Affiliates are party to any agreement or arrangement, whether written or oral, that either would or would be reasonably likely to result in Payments to Third Parties following the Effective Date. For clarity, and without limiting the definition of "Payments to Third Parties," the foregoing is not intended to extend to payments to be made to subcontractors of either Party.

# ARTICLE 6 MANUFACTURE AND SUPPLY

- **6.1** <u>Overview</u>. The provisions of this <u>ARTICLE 6</u> shall apply to the Manufacture of the Product unless otherwise agreed by mutual Party Written Consent.
- Global Manufacturing Plan. Prior to the Effective Date, the JDT adopted a Joint Development Plan and Joint Budget (each, as defined in the Collaboration Agreement) that govern the global Development, Manufacturing, and regulatory activities of the Parties with respect to the Product under the Collaboration Agreement. As promptly as practicable following the Effective Date, the JCMCT shall (a) update the portions of such Joint Development Plan and Joint Budget relating to Manufacturing and CMC Development to the extent necessary to (i) align the contents thereof with this Agreement and the Approved Plans hereunder, and (ii) otherwise reflect the global Manufacturing and CMC Development activities of the Parties with respect to the Product throughout the Territory, including the topics set forth in this Section 6.2, (provided that such plan and budget shall include a high-level summary prepared by SGI with respect to the Royalty Territory) and (b) submit such updated plan and budget to the JSC for approval (as approved by the JSC, such plan and budget, collectively, the "Global Manufacturing Plan"). Following its approval by the JSC, the Global Manufacturing Plan under this Agreement shall replace the portions of the Joint Development Plan and Joint Budget under the Collaboration Agreement for purposes of Manufacturing and CMC Development for the Product. On an annual basis, or more often as the Parties deem appropriate, the JCMCT shall prepare amendments to the then-current Global Manufacturing Plan, including any amendments proposed by SGI with respect to the Royalty Territory, for approval by the JSC. In the event of any inconsistency between the Global Manufacturing Plan and this Agreement, the terms of this Agreement shall prevail. The Global Manufacturing Plan shall include: (A) the Parties' global Manufacturing strategy for the Product to meet the forecasts set forth in the Approved Plans or otherwise agreed by the JCMCT, in each case, throughout the Territory, together with appropriate safety stock of key intermediates, drug substance and drug product; (B) a plan for CMC Development and other related activities, including activities related to process improvements that could materially impact cost, efficiency, or stability of supply, and line extensions; (C) a Supply Chain Management plan; and (D) a strategy for risk management and

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evaluating the need for second or additional source Manufacturing of the Product, including a plan for monitoring the performance of CMOs.

## **6.3** <u>Manufacturing Transition; Supply and Quality Agreements.</u>

Notwithstanding any determinations of the JSC or the JCMCT made prior to the Effective 6.3.1 Date, the Parties agree that SGI will be responsible for global Manufacturing for the Product following the Effective Date, subject to the oversight of the JCMCT and otherwise in accordance with the Global Manufacturing Plan and this Agreement; provided, that the Selling Party shall perform Packaging and Labeling and Sales and Distribution for the Product in such Party's Party Major Market(s) and, as to SGI, the Royalty Territory. Accordingly, [\*] following the Effective Date, the JCMCT shall develop a plan to transition global Manufacturing for the Product (but not including Packaging and Labeling or any Sales and Distribution activities, in each case, for the Genmab Major Market) to SGI (the "Manufacturing Transition Plan"). The Manufacturing Transition Plan will provide for, where possible, the assignment or an appropriate delegation to SGI (including the grant of a sublicense to SGI, where appropriate), or other appropriate disposition or substitution consistent with this ARTICLE 6, of existing agreements between Genmab or its Affiliates and contract manufacturing organization ("CMOs") with respect to supply of the Product, which agreements are listed on **Schedule 6.3** ("Existing Product CMO Agreements," and the relevant Third Party CMOs that are counterparties thereto, the "Existing Product CMOs"). Each Party shall use Commercially Reasonable Efforts to implement the Manufacturing Transition Plan and complete the transition of Manufacturing contemplated by this Section 6.3.1 as promptly as practicable, and in any event within the timelines contemplated therein. Unless otherwise agreed by the JSC, SGI shall continue to use the Existing Product CMOs for the Manufacturing of the Product in the Major Markets for the remaining terms of such Existing Product CMO Agreements. Without limiting the foregoing, with respect to Clinical Supply for the Major Markets, the JSC shall agree on whether to renew any then-existing agreements with CMOs (including the Existing Product CMOs) for the Clinical Supply of the Product or to transition the Clinical Supply of Product to an alternative CMO (or to a Party or its Affiliate, if so determined by the JCMCT in accordance with Section 6.4) at a reasonable time prior to the expiration of the remaining term of each then-existing agreement with a CMO for the Clinical Supply of the Product (including the Existing Product CMOs). With respect to the Commercial Supply of the Product for the Territory, the Parties acknowledge that Genmab is in the process of negotiating a commercial supply agreement with [\*] for the Manufacture of the Product for the Territory, and that, subject to the consent of [\*], Genmab and SGI will finalize the commercial supply agreement in close consultation with [\*] after the Effective Date and, to the extent reasonably possible, the Parties shall make SGI the contracting party to such agreement instead of Genmab, or mutually agree on an alternative path to assign or transition such agreement to SGI.

**6.3.2** Following the assignment, sublicensing, or other disposition of such Existing Product CMO Agreements to SGI in accordance with Section 6.3.1, the Parties shall (a) transition to a new clinical supply agreement and quality agreement that provide for SGI or its Affiliate to Manufacture and supply to Genmab Clinical Supply in accordance with Genmab's requirements for Clinical Supply and terminate the existing Clinical Supply Agreement and related quality agreement in connection with such transition, and (b) enter into a supply agreement (the "Commercial Supply Agreement") and quality agreement between SGI and Genmab, as contemplated by Section 6.2.1 of the Collaboration Agreement and consistent with this Agreement,

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setting forth the terms and conditions on which SGI or its Affiliate shall Manufacture and supply, or have Manufactured and supply, to Genmab Commercial Supply for the Genmab Major Market, and, in the case of the quality agreement, quality-related matters relating to such Manufacture. Such supply and quality agreements shall be prepared by or under the oversight of the JCMCT, but shall be mutually agreed and entered into by the Parties or their respective Affiliates. The terms and conditions of such supply agreement will set forth the details of a supply arrangement with financial terms that support the supply of Product and sharing of Manufacturing Costs consistent with this Agreement and otherwise reflect customary terms and conditions for the supply and quality of pharmaceutical products in the context of a collaboration with a profit sharing arrangement such as the Collaboration, including with respect to forecasting and ordering, payment terms, financial and compliance audits, the engagement of subcontractors, a fair and equitable allocation of Product between the Parties and their Affiliates in the event of any defects or Product shortfalls, and representations and warranties. Such quality agreement shall govern processes for product distribution holds, recalls, clinical holds, or market withdrawals (as set forth in Section 4.4) and any other quality control and quality assurance-related activities agreed between the Parties.

- **6.4** Existing CMOs; Second Source. The JCMCT will, from time to time, evaluate the need for a second or additional source for the Manufacturing (other than Packaging and Labeling), in whole or in part, of the Product or any component thereof (*i.e.*, source(s) other than the then-current source(s) for such Manufacturing of the Product or its components) for specific countries globally, and make any recommendations agreed by the JCMCT with respect to the foregoing to the JSC for approval. Unless otherwise agreed by the JSC, the Parties shall continue to use the Existing Product CMOs for the Manufacturing of the Product in Major Markets as well as the Royalty Territory, and JSC approval shall be required before either Party engages in second or additional source Manufacturing for the Product.
- **6.5** <u>Manufacturing Costs</u>. In the event that the Parties develop a costing methodology for Manufacturing Costs under <u>Section 1.71.2</u>, such methodology shall be developed by the JCMCT and approved by the JFT before its application in a relevant Commercial Supply Agreement or other supply agreement entered into under this Agreement. SGI will be solely responsible for all Commercial Packaging and Labeling Costs and Manufacturing Costs for Product for the Royalty Territory, and after the expiration of the Royalty Term in a country, SGI will be solely responsible for those additional costs no longer included in [\*] that are directly attributable or reasonably allocable to such country as set forth in <u>Sections 1.3.4</u>, <u>1.3.5</u> and <u>1.3.6</u>.
- **6.6** <u>Inventory.</u> The Parties shall each track and record on a Quarterly basis their respective inventory of Product (including components thereof) and their respective costs of Packaging and Labeling to enable the calculation of Allowable Expenses and Development Costs for the Product. Each Party shall provide a report to the JFT and JCMCT of such inventory and costs on a Quarterly basis.
- **6.7** <u>Product Shortfall; Allocation</u>. In the event of any material Product shortfall or defect, the JCMCT will develop a methodology to fairly and equitably allocate Product supply between the Parties and their Affiliates on a global basis (with first priority given to the Major Markets relative to the Royalty Territory), and propose such global allocation and any changes thereto for review and approval by the JSC.

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# ARTICLE 7 MEDICAL AFFAIRS ACTIVITIES

- 7.1 Overview. Subject to the Combined Major Market Medical Affairs Plan and oversight by the JMAT, JDC, JCC and the JSC, and the terms of this Agreement (including ARTICLE 3 with respect to Genmab's right to provide MSLs in the United States), each Party shall have the right and responsibility for Medical Affairs Activities in support of the Product in its Party Major Market(s) in accordance with this Agreement, including as provided in this ARTICLE 7, including by performing activities for such Party Major Market(s) as follows: (a) preparing materials for use in connection with Medical Affairs Activities in its Party Major Market(s). (b) preparing training materials and training programs for personnel engaged in such Medical Affairs Activities and implementing such training, and (c) making decisions with respect to its Party Tactical Matters in connection with such Medical Affairs Activities; provided, that, in each case ((a) through (c)), such activities shall be consistent with the Party Major Market Medical Affairs Plan, Combined Major Market Medical Affairs Plan, and US Coordination Plan, including the tactical and strategic matters described in such plans, and otherwise conducted in accordance with this Agreement (including ARTICLE 3 with respect to the United States). Notwithstanding the foregoing, each Party will be permitted to list the Product as part of its portfolio in any country in the Major Markets (including the other Party's Party Major Market(s)) in settings where the Party has a "corporate presence" (e.g., within a booth at a conference or congress), including by providing totems or videos with respect to the Product in any such setting; *provided*, that (i) any such totems or videos and any other signs or materials used by a Party in connection therewith comply with the Medical Affairs Plans, the Publication Charter and all other applicable terms and conditions of this Agreement, (ii) the activities of the Parties at conferences and congresses in the United States will be subject to the US Coordination Plan, and (iii) in any other country in the Major Markets, any request for information relating to the Product by an applicable HCP requesting information in the other Party's Party Major Market(s) will be referred to the other Party if practicable (i.e., the applicable HCP will be directed to the other Party's booth, if available).
- 7.2 <u>Combined Major Market Medical Affairs Plan.</u> The Medical Affairs Activities in support of the Product in the Major Markets shall be described in a plan and budget for Medical Affairs Activities and Medical Affairs Costs (a "<u>Combined Major Market Medical Affairs Plan</u>"). The JMAT shall prepare the first draft of the Combined Major Market Medical Affairs Plan for review and approval by the JSC at least [\*] months prior to the first anticipated Launch of the Product in the Major Markets (as such date is reasonably projected by the JDC), and cover a period of [\*] years ([\*] year forecasted and [\*] year projections). Once agreed by the JMAT, the JMAT shall recommend the Combined Major Market Medical Affairs Plan to the JSC for approval. The Combined Major Market Medical Affairs Plan shall be updated at least annually, and all updates and amendments shall be reviewed and approved by the JMAT and then submitted to the JSC for approval. The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees. The Combined Major Market Medical Affairs Plan and subsequent revisions thereto will include, with respect to the Major Markets (a) the Parties' strategy for Medical Affairs Activities

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for the Product (including the relative responsibilities of the Parties with respect thereto), (b) an agreed range for the aggregate number of MSLs or MSL FTEs expected to be deployed in the Major Markets either by country or region as reasonably determined by the JMAT, (c) key performance indicators either by country or region, as reasonably determined by the JMAT, that the Parties shall implement, and that shall apply to the activities of the MSLs of each Party in the Major Markets, (d) such information as the JMAT believes necessary for the successful medical affairs support of the Product, such as overall medical strategy, the medical narrative, global advisory boards, publication plans, outcomes/real world evidence strategy, and strategy for investigator- initiated trials and investigator-sponsored research in the Major Markets, and (e) [\*] year forecasts and projections for an additional [\*] years for such topics included in the Combined Major Market Medical Affairs Plan. The topics included in the Combined Major Markets and on a regional basis. In the event of any inconsistency between (i) the Combined Major Market Medical Affairs Plan and this Agreement, the terms of this Agreement shall prevail and (ii) the Combined Major Market Medical Affairs Plan shall prevail.

#### 7.3 Party Major Market(s) Medical Affairs.

Party Major Market Medical Affairs Plans. The Medical Affairs Activities in support of 7.3.1 the Product (a) in the SGI Major Markets shall be described in a high-level plan and corresponding budget (collectively, the "SGI Major Market Medical Affairs Plan") and (b) in the Genmab Major Market shall be described in a high-level plan and corresponding budget (collectively, the "Genmab Major Market Medical Affairs Plan"), in each case ((a) and (b)), that describe the strategy for Medical Affairs Activities for the Product in the corresponding Party Major Market(s). In addition, the SGI Major Market Medical Affairs Plan will incorporate the Medical Affairs Activities set forth in the US Coordination Plan. Each Party shall prepare their own Party Major Market Medical Affairs Plan and provide it to the JMAT, which shall review such plans for consistency with the Combined Major Market Medical Affairs Plan (subject to Section 2.10.5(c)). The initial draft of each Party Major Market Medical Affairs Plan shall be submitted to the JMAT within [\*] of submission of the initial draft of the Combined Major Market Medical Affairs Plan to the JMAT in accordance with Section 7.2. The Party Major Market Medical Affairs Plans shall be updated at least annually, and all updates and amendments shall be reviewed and approved by the JMAT for consistency with the Combined Major Market Medical Affairs Plan. The Parties shall agree on a timeline for conducting all such reviews and approvals that accommodates the Parties' respective planning and budgeting purposes and allows for necessary or reasonably useful coordination between the Committees.

**7.3.2** <u>Medical Affairs Reports for the Major Markets</u>. Within thirty (30) days after the end of each Quarter, each Party shall provide to the JMAT such information regarding the Medical Affairs Activities in support of the Product in its respective Party Major Market(s) as the JMAT or the other Party may reasonably request.

#### 7.4 <u>Medical Affairs Standards of Conduct.</u>

**7.4.1** <u>Diligence; Compliance</u>. Each Party shall carry out the tasks assigned to it under the Medical Affairs Plans in a timely and effective manner and in compliance with

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Applicable Laws and applicable industry compliance standards.

**7.4.2** <u>Diligence Obligations</u>. Each Party shall use Commercially Reasonable Efforts to perform Medical Affairs Activities in support of the Product in its Party Major Market(s) following obtaining Regulatory Approval therefor with respect to the applicable country or territory in accordance with and to the extent provided in the Combined Major Market Medical Affairs Plan, the applicable Party Major Market Medical Affairs Plan, and otherwise in accordance with this Agreement.

## ARTICLE 8 REGULATORY MATTERS

#### **8.1** Regulatory Matters.

- Global Regulatory Plan. As part of the Global Development Plan, (a) the Parties, acting through the JRT and JDC, shall jointly prepare a global regulatory plan for the Product or the portions of the Global Development Plan describing the regulatory actions to be taken by each Party in the Territory (provided that such plan or portions of the Global Development Plan shall include a high-level summary prepared by SGI with respect to the Royalty Territory) (such plan or portions of the Global Development Plan are referred to herein as the "Global Regulatory Plan") and (b) each Party shall prepare a regulatory plan for the Product or the portions of the Global Regulatory Plan describing the regulatory actions to be taken by such Party in or for its Major Market(s) consistent with the Global Regulatory Plan and the strategic matters described therein (each, a "Party Regulatory Plan"), in each case ((a) and (b)), that describe how such activities shall be coordinated if necessary, including (i) the content of the Core Data Sheet for the Product (prepared in accordance with Section 8.1.6) that will be used to support global submissions to Regulatory Authorities, (ii) planned meetings with Regulatory Authorities regarding the Product, (iii) plans for INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for the Product, and (iv) the amount of annual or other fees projected to be assessed by Regulatory Authorities. Each Party Regulatory Plan shall be reviewed by the JRT for consistency with the Global Regulatory Plan (for clarity, if the JRT does not agree that a Party Regulatory Plan is consistent with the Global Regulatory Plan, such dispute will be escalated to the JDC and resolved in accordance with Section 2.10.5(b)). Without limiting the foregoing, the JRT (and JDC) shall coordinate with the JCMCT with respect to the regulatory aspects of CMC Development and the regulatory activities related to CMC Development that are addressed in the Global Development Plan and the Global Regulatory Plan. In the event of (x) any inconsistency between a Global Regulatory Plan and this Agreement, the terms of this Agreement shall prevail, and (y) any inconsistency between a Party Regulatory Plan and the Global Regulatory Plan, the terms of the Global Regulatory Plan shall prevail. For clarity, unless otherwise determined by the JRT, neither Party nor the JRT shall be obligated to prepare the Global Regulatory Plan or the Party Regulatory Plans as stand-alone planning documents, and as used in this Agreement, the terms "Global Regulatory Plan" and "Party Regulatory Plans" refer to the relevant content whether it is included in a stand-alone document, incorporated into an applicable Approved Plan, or otherwise.
- **8.1.2** <u>Ownership</u>. Notwithstanding Section 7.2 of the Collaboration Agreement, as between the Parties, legal title to and legal ownership of all INDs, Drug Regulatory

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Approval Applications, Regulatory Approvals and related filings for the Product (a) in the Genmab Major Market shall be held by Genmab or its Affiliates, and (b) in the SGI Major Markets and the Royalty Territory shall be held by SGI or its Affiliates (such Party holding legal title to and legal ownership of such materials in the applicable country or region being referred to as the "Lead Regulatory Party"); provided, that (i) Section 7.2 of the Collaboration Agreement shall not be superseded by this Agreement to the extent that this Agreement would otherwise reallocate responsibility with respect to regulatory materials relating to Drug Conjugation Technology (as defined in the Collaboration Agreement), and (ii) sponsorship of Clinical Trials and ownership of INDs during the conduct of Clinical Trials shall be in accordance with Section 4.6.2. Subject to the foregoing, to the extent any INDs, Drug Regulatory Approval Applications, Regulatory Approvals, and related filings for the Product existing as of the Effective Date (or at any time during the Term) are not owned by the Lead Regulatory Party under this Agreement, the other Party hereby assigns to the applicable Lead Regulatory Party all of its right, title, and interest in and to all such INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for the Product that it or any of its Affiliates owns. Such other Party shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary to effectuate such assignment.

Responsibilities. With respect to each country in the Territory, the Lead Regulatory Party shall, in accordance with the Global Regulatory Plan, Party Regulatory Plan (if applicable), and the terms and conditions of this Agreement: (a) be responsible for the day-to-day implementation of the regulatory activities required to obtain and maintain Regulatory Approval of the Product in the applicable country (*provided* that any decision to file a DAA for the Product anywhere in the Territory must be approved by the JSC); (b) subject to consistency with the Core Data Sheet, be responsible for labeling of the Product in the applicable country for which it is the Lead Regulatory Party; (c) take the lead with respect to communications with the Regulatory Authorities in such country; and (d) designate a representative to serve as the designated regulatory official for the Product in such country for purposes of receiving and delivering communications from the Regulatory Authorities in such country. The other Party will cooperate with the Lead Regulatory Party as reasonably necessary, and solely with respect to the Major Markets, the costs thereof will be Development Costs.

**8.1.4** Regulatory Authority Submissions and Correspondence. In accordance with the Global Development Plan, Global Regulatory Plan, and Party Regulatory Plan (if applicable), the Lead Regulatory Party shall be responsible for the preparation of all documents and other correspondence to be submitted to Regulatory Authorities pertaining to the Product (other than the Core Data Sheet, which shall be subject to Section 8.1.6(a)). Solely with respect to the Major Markets, the Lead Regulatory Party shall provide to the other Party drafts of any material documents or correspondence to be submission so that the other Party may review and comment on such documents or correspondence prior to submission, and the Lead Regulatory Party shall take such comments under good faith consideration. Solely with respect to the Major Markets, the Lead Regulatory Party shall as promptly as practicable (and, in any event, within [\*] Business Days of its receipt) provide the other Party with copies of any material documents or correspondence received from a Regulatory Authority in a Major Market pertaining to the Product. Neither Party shall be required to translate any documents received or submitted to

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a Regulatory Authority except to the extent required by such Regulatory Authority.

**8.1.5** Meetings with Regulatory Authorities. Subject to the Global Development Plan, the Global Regulatory Plan, and the Party Regulatory Plan (if applicable), the Lead Regulatory Party with respect to a country shall be responsible for conducting all meetings and telephone or video conferences related to the Product with Regulatory Authorities in such country, including all Product labeling discussions. To the extent permitted under Applicable Law and with the prior consent of the relevant Regulatory Authority, the other Party shall have the right to have [\*] representative attend all such in-person meetings and material telephone conferences or videoconferences with Regulatory Authorities solely in the Major Markets, and to the extent practicable the Lead Regulatory Party shall schedule such meetings in consultation with the other Party to permit such attendance and participation by the other Party.

#### **8.1.6** Approval of Core Data Sheet and CMC Information.

Subject to the terms and conditions of this Section 8.1.6(a), SGI shall be responsible for preparing a draft Core Data Sheet for the Product and may propose amendments thereto from time to time during the Term. The JRT, together with the CDS Working Group, will (i) review a draft Core Data Sheet prepared by SGI and any amendments thereto proposed by SGI, and (ii) agree on a proposed version of the Core Data Sheet to submit to the JDC. The JDC will then review such version and approve a draft of the Core Data Sheet for submission to the JSC for the JSC's approval. The Core Data Sheet and any amendments thereto must be approved by the JSC. Notwithstanding the foregoing, each Party shall (A) be responsible for creating and updating the local product information for the Product in its Party Major Market(s) (and SGI shall have such responsibility for the Royalty Territory) and (B) solely with respect to such Party's Major Market(s) shall submit such information to the JRT and CDS Working Group. All such local product information (including with respect to the Royalty Territory) shall be subject to approval by the JSC if any substantive deviations are made from the thencurrent Core Data Sheet as last approved by the JSC. The JRT and CDS Working Group shall decide if any such local product information requires approval of the JSC. Notwithstanding anything herein to the contrary, (1) the Lead Regulatory Party shall be responsible for maintaining the Core Data Sheet, including local product information, for each country in the Territory for which it is Lead Regulatory Party, and (2) any changes to the local product information required by Applicable Law or a Governmental Authority in any Major Market may be made by the applicable Lead Regulatory Party irrespective of any Committee review or approval contemplated by this Section 8.1.6(a); provided, that any such changes shall be communicated by the applicable Party to the JRT and the CDS Working Group in a timely manner. For the avoidance of doubt, SGI shall be responsible for (x) maintaining the Core Data Sheet for each country in the Royalty Territory, (v) making any amendments thereto subject to JSC approval, and (z) creating, updating and maintaining any local product information for the Product for each country in the Royalty Territory without an obligation to obtain JSC approval unless such local product information would constitute a substantive deviation from the then-current Core Data Sheet as last approved by the JSC, in which case such local product information must be approved by the JSC. For clarity, the Core Data Sheet and any amendment thereto or local product information related thereto, in each case, that is approved by the JSC shall be deemed approved for all purposes under this Agreement irrespective of whether the JRT, CDS Working Group, or JDC formally approved a particular document or the information contained therein.

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- **(b)** The JDC in collaboration with the JCMCT shall review and approve the CMC components of any Drug Regulatory Approval Application in the Major Markets; *provided*, that if the CMC components of any Drug Regulatory Approval Application for the Product in the Major Markets have previously been approved as set forth above, the Lead Regulatory Party may request permission from the JCMCT to submit such components (or subset thereof) to the applicable Regulatory Authorities without such prior review and approval (such permission to be granted only by the JCMCT).
- **8.1.7** Advertising and Promotion. The Lead Regulatory Party in the applicable country shall be the point of contact and the responsible Party for Regulatory Authorities with respect to any Promotional Materials relating to the Product consistent with the Combined Major Market Plans. Section 8.1.4 shall apply with respect to the other Party's rights to review and comment on any such correspondence with or submissions to Regulatory Authorities in connection therewith.
- **8.1.8** <u>Drug Naming Regulatory Approvals</u>. Subject to <u>Section 11.2.1</u>, the Lead Regulatory Party in the applicable country will take the lead in drug naming procedures with the Governmental Authorities and Regulatory Authorities relating to the Product consistent with <u>Section 11.2</u>. To the extent applicable, <u>Section 8.1.4</u> shall apply with respect to the other Party's rights to review and comment on any such correspondence with or submissions to Regulatory Authorities in connection therewith, *provided* that such activities in the Major Markets are in accordance with the Combined Major Market Plans and performed in consultation with the other Party through the JRT or JDC.
- **8.1.9** Rights of Reference. The Lead Regulatory Party shall have the right to cross reference, file or incorporate by reference any regulatory submission or drug master file (and any data contained therein) for the Product, or any component thereof, made or maintained in any country in the Territory (including all Regulatory Approvals) by the other Party in order to support regulatory submissions that the Lead Regulatory Party is permitted or required to make under this Agreement for the Product and to enable either Party to fulfill its obligations, or exercise its rights, under this Agreement.
- 8.1.10 Notice of Inspection, Investigation or Inquiry. If any Governmental Authority, including any Regulatory Authority (a) contacts a Party with respect to the alleged improper Development, Manufacture, or Commercialization of the Product in the Territory, (b) conducts, or gives notice of its intent to conduct, a non-routine inspection at such Party's facilities (or the facilities of any clinical trial site or vendor) to the extent related to the Product, or (c) takes, or gives notice of its intent to take, any other regulatory or enforcement action with respect to any activity of such Party that could reasonably be expected to adversely affect any Development, Manufacture, or Commercialization activities with respect to the Product in the Territory, then such Party shall immediately notify the other Party of such contact, inspection or notice ("Product Inquiry Notice") within [\*] Business Day of receipt thereof and shall to the extent reasonably practicable and permitted under any relevant subcontracting agreement permit the other Party to be present at the site of any such inspection, investigation or inquiry to be conducted by such Governmental Authority in connection with such Product Inquiry Notice. The contacted,

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inspected or notified Party ("Affected Party") shall provide such other Party with copies of all pertinent information and documentation issued by any such Regulatory Authority as promptly as practicable (and, in any event, within [\*]) after receipt, and the other Party, through the JDC in collaboration with the JRT and/or JCMCT, as applicable, shall have the right to oversee and comment on the preparation of any responses that pertain to the Product; *provided*, that (i) where the time limit for a response to the competent Regulatory Authorities would prevent the Parties from consulting the JDC and JRT and/or JCMCT in advance of such response, the Affected Party shall immediately notify the other Party's representatives on JDC and JRT and/or JCMCT and send a copy of any response not later than [\*] after the response to the competent Regulatory Authorities is submitted, and (ii) final decision-making authority with respect to such submissions shall belong to the Lead Regulatory Party unless otherwise set forth in the quality agreement contemplated by Section 6.3; provided, further, that any such responses that relate to critical issues or significant non-compliance may, to the extent practicable, be escalated by either Party to the JSC for review and approval of such responses on an expedited timeline to comply with time periods to respond as required by Applicable Law. For the avoidance of doubt, nothing in this Section 8.1.10 shall prevent the Lead Regulatory Party from taking any action reasonably necessary to comply with Applicable Law or address an urgent or serious health or safety matter.

8.2 Pharmacovigilance; Adverse Event Reporting. The Parties entered into a Pharmacovigilance Agreement, effective [\*], covering the management of safety information, adverse event reporting and the maintenance of a global safety database with respect to the Product. Prior to the First Regulatory Approval of the Product, the Parties shall amend the existing pharmacovigilance agreement or enter into a new pharmacovigilance agreement to address the Commercialization and other activities with respect to the Product contemplated by this Agreement. The amended or new pharmacovigilance agreement, as applicable, shall provide that (a) SGI will maintain the global safety database for the Product and be responsible for drafting and submitting periodic reports to Regulatory Authorities in any country or jurisdiction for which it is the Lead Regulatory Party, and SGI will provide to Genmab copies of such reports throughout the Territory, (b) Genmab and SGI will exchange all safety data as provided in the pharmacovigilance agreement(s) for the purpose of Genmab maintaining a mirror copy of the SGI global safety database for the Product, and (c) Genmab will be responsible for drafting periodic reports to Regulatory Authorities in any country or jurisdiction for which it is the Lead Regulatory Party, and Genmab will provide to SGI copies of such reports. To the extent the terms and conditions of this Agreement conflict or are otherwise inconsistent with the terms of such pharmacovigilance agreement(s), the terms and conditions of the pharmacovigilance agreement(s) shall prevail with respect to drug safety matters (including adverse event reporting or the maintenance of a global safety database) and the terms and conditions of this Agreement shall prevail with respect to all other matters.

# ARTICLE 9 COMPLIANCE

**9.1** <u>Compliance.</u> In connection with all activities undertaken pursuant to this Agreement or otherwise relating to the Product, each Party hereby covenants and agrees to comply, and cause its Affiliates to comply, with the then-current Pharmaceutical Research and Manufacturers of America (PhRMA) Code or such similar industry code as may exist in each country or jurisdiction in the Territory in which such Party undertakes activities under this

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Agreement, including the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (EFPIA HCP Code), the EFPIA HCP/HCO Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA Disclosure Code) and the codes of conduct approved by the national industry associations of the individual EFPIA member countries (the "Industry Codes"), and (c) all Applicable Laws. In particular:

- **9.1.1** Each Party shall (a) instruct its personnel not to, and shall ensure that its personnel do not, take any action that could jeopardize the goodwill or reputation of the Product or the other Party (or any of this Affiliates), (b) maintain a corporate compliance program that includes a mechanism for its employees to report, anonymously if they choose (and where legally permissible), any concerns about potential illegal or out-of-policy activity, and that will require such Party to investigate any such reports, and (c) immediately notify the other Party of the substance of any such report in the event that (i) such report concerns illegal activity that potentially impacts the Product, and (ii) such Party has a reasonable basis for believing such report has merit; provided, that, in each case ((i) and (ii)), a Party shall not be required to disclose any information regarding individual employees alleged to have violated any Applicable Laws, or to have failed to comply with this Agreement, except to the extent necessary to report the resolution of alleged violation of Applicable Laws or failure to comply with this Agreement.
- **9.1.2** In performing the activities contemplated by this Agreement, neither Party shall make any payment, either directly or indirectly, of money or other assets (hereinafter collectively referred as a "Payment") to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "Officials") where such Payment would constitute violation of any Applicable Law or the applicable Industry Codes. In addition, no Party shall make any Payment, either directly or indirectly, to Officials if such Payment is for the purpose of unlawfully influencing decisions or actions with respect to the subject matter of this Agreement. No employee of a Party or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by such Party or its agents to any Third Party in violation of terms of this Section 9.1.2 or any other provision of this Agreement.
- **9.1.3** With respect to the Product, each Party must track and report (a) all payments made by that Party or any of its Affiliates to health care providers and health care organizations, and (b) such other information as may be required to comply with its obligations under Applicable Law or the applicable Industry Codes.
- **9.1.4** Genmab and SGI agree to abide by all Data Protection Laws with respect to their processing of personal data in the course of their performance under this Agreement. Upon the reasonable request by either Party, the Parties shall negotiate and enter into such mutually agreeable data protection agreement(s), or amend that certain [\*] Data Processing Agreement, dated as of [\*], by and between the Parties, to further clarify their respective roles in complying with the Data Protection Laws.
- **9.1.5** Genmab and SGI agree to abide by all Applicable Law of all applicable Governmental Authorities, including antitrust and competition laws with respect to not restricting

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passive sales among EU member states.

- **9.1.6** Each Party agrees to provide any information or documentation related to this Agreement or the activities hereunder required by the other Party in order to enable such other Party to comply with Applicable Law or any Third Party agreements relating to the Collaboration.
- **9.2** Export. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to SGI or Genmab from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental Regulatory Approval, without first obtaining the written consent to do so from the appropriate Governmental Authorities.

# ARTICLE 10 REPRESENTATIONS AND WARRANTIES; COVENANTS

- **10.1** <u>Mutual Representations and Warranties</u>. Each Party represents and warrants to the other Party, as of the Effective Date, that:
- **10.1.1** <u>Corporate Power</u>. It is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.
- **10.1.2** <u>Due Authorization</u>. It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person(s) executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.
- **10.1.3** <u>Binding Agreement</u>. This Agreement is legally binding upon it and enforceable against it in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may otherwise be bound, nor violate any material law or regulation of any Governmental Authority having jurisdiction over it.
- 10.1.4 No Conflicts. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not and will not (a) conflict with or violate in any material respect any requirement of Applicable Law or any judgment, decree, order, regulation, or rule of any Governmental Authority by which such Party is bound or subject; (b) conflict with or violate the organizational documents of such Party; or (c) result in a breach (or any event which, with notice or lapse of time or both, would constitute a breach) of any material term or provision of, or constitute a material default under any contractual obligations of, such Party or any of its Affiliates.
- 10.2 <u>No Debarment</u>. In the course of the Development of the Product pursuant to the Collaboration Agreement, each Party has not used and, during the Term, will not use, any employee or consultant that is debarred, disqualified, or restricted by any Governmental

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Authority or Regulatory Authority or, to the best of such Party's knowledge, is the subject of debarment, disqualification, or restriction proceedings by any Governmental Authority or Regulatory Authority. If either Party learns that it or any employee or consultant performing services on its behalf under this Agreement has been debarred, disqualified, or restricted by any Governmental Authority or Regulatory Authority, or has become the subject of debarment, disqualification, or restriction proceedings by any Governmental Authority or Regulatory Authority, such Party shall promptly notify the other Party and, in the case of an employee or consultant, shall prohibit such employee or consultant from performing on its behalf under this Agreement.

DISCLAIMER. **NEITHER PARTY MAKES EXPRESS IMPLIED** 10.3 ANY OR REPRESENTATION OR WARRANTY EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 10 OR ELSEWHERE IN THIS AGREEMENT, INCLUDING ANY REPRESENTATION OR WARRANTY REGARDING THE VALIDITY OR SCOPE OF ITS PATENT RIGHTS OR THAT THE MANUFACTURE, USE OR SALE OF THE PRODUCT WILL NOT INFRINGE THE PATENT RIGHTS OF THIRD PARTIES, OR ANY REPRESENTATION OR WARRANTY AS TO THE VALUE, ADEQUACY, FREEDOM FROM FAULT OF, OR QUALITY, EFFICIENCY, CHARACTERISTICS OR USEFULNESS OF, OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF, THE PRODUCT, THE LIKELIHOOD OF RECEIVING REGULATORY APPROVAL FOR THE PRODUCT IN ANY JURISDICTION, OR THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

#### ARTICLE 11 INTELLECTUAL PROPERTY

11.1 <u>Copyrights</u>. All copyrights for Promotional Materials or other Product-specific packaging, educational or training materials, in each case, jointly prepared or authored by or for the Parties or their respective Affiliates in furtherance of the Collaboration shall be jointly owned by the Parties; *provided*, that (a) such materials may not be used outside the Collaboration without the Party Written Consent of the other Party and (b) the foregoing shall not affect or constitute a waiver of any copyright rights that a Party may have in its individually owned materials that were incorporated into a jointly owned copyrighted material.

#### **11.2** Product Trademarks.

11.2.1 Both Parties shall use the same brand name and associated trademarks for the Product in all countries in which the global trademark can reasonably be secured. The Product shall be sold under the same trademark and a generic or international non-proprietary name, and marketed using same logos, slogans, trade dress, domain names, and other similar intellectual property rights throughout the Territory to create a worldwide brand for the Product unless a Party has good cause to use a different brand name (such as for regulatory, inability to secure registration, or Third Party infringement reasons) in a country or territory where it is the Selling Party, informs the JCC thereof, and the JCC approves thereof (excepting the generic or international non-proprietary name, hereinafter, "Product Trademarks"); provided, that the Product Trademarks shall not use, be comprised of, or incorporate the [\*] (hereinafter, "Other

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Marks") without SGI's or Genmab's, as applicable, prior Party Written Consent. For clarity, "Other Marks" includes [\*]. The Product Trademarks shall be initially jointly owned by the Parties worldwide and the initial applications for registration for such Product Trademarks shall be filed and prosecuted by the Parties jointly using outside counsel mutually acceptable to the Parties (with the associated costs of engaging such outside counsel included in Trademark Costs); except that the domain names included in the Product Trademarks will be owned solely by and registered in the name of one Party (as determined by the JCC), and such Party shall be deemed the "Trademark Owner" (as defined below) with respect thereto. Upon registration of the Product Trademarks in the applicable country or territory, the Parties shall assign such Product Trademarks (a) to [\*] (the applicable Party, the "Trademark Owner"). All registrations for Product Trademarks shall be maintained by the Trademark Owner (at its expense; provided, that Out of Pocket Costs of such maintenance for the Major Markets shall be treated as Trademark Costs). The Parties agree to handle Trademark Costs for the Product under this Agreement such that SGI or Genmab will pay its outside counsel, as applicable, and (i) to the extent such Trademark Costs are directly attributable or reasonably allocable to the Major Markets, the other Party will reimburse the paying Party [\*] of such Trademark Costs paid to such outside counsel (ii) to the extent such Trademark Costs are directly attributable or reasonably allocable to the Royalty Territory, solely if Genmab was the paying party with respect to such Trademark Costs, SGI shall reimburse Genmab for all such costs paid to its outside counsel. Each Party agrees that it will use the trademark registration symbol ® or TM, as appropriate, in connection with the Product Trademarks. Genmab and SGI agree to cooperate with respect to execution and delivery of such additional instruments or documents as shall be necessary to ensure each Party's rights and interest in and to the Product Trademarks.

- **11.2.2** Each Party agrees to maintain suitable quality standards with respect to the Product it provides in connection with the Product Trademarks. Neither Party shall use outside the Collaboration any trademark that is substantially the same as or deceptively or confusingly similar to the Product Trademarks.
- 11.2.3 This <u>Section 11.2</u> supersedes Section 14.6 of the Collaboration Agreement with respect to the Product.

## 11.3 <u>Infringement of Trademarks</u>.

promptly upon learning of any actual or alleged infringement, or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offenses or any such claims thereof relating to the Product Trademarks brought by a Third Party against a Party or any of its Affiliates (hereinafter "Trademark Infringement Claims"). Upon learning of such Trademark Infringement Claim, the Party or Parties against which such claim is made shall take all reasonable and appropriate steps to resolve the Trademark Infringement Claim, and give reasonable consideration to the other Party's suggestions regarding such Trademark Infringement Claim. All Out of Pocket Costs incurred in bringing, maintaining and prosecuting any action described in this Section 11.3.1 (including for outside counsel) shall be (a) included in [\*] to the extent such Trademark Infringement Claim relates to the [\*] Markets and (b) otherwise borne solely by [\*] for the [\*]. The non-resolving Party shall cooperate with the resolving Party in connection with any Trademark Infringement Claims, and all reasonable fees and expenses incurred for outside counsel

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and other reasonable Out of Pocket Costs incurred by such Party in providing such cooperation shall be (i) included in [\*] to the extent such Trademark Infringement Claim relates to the [\*] Markets and (ii) otherwise borne solely by [\*] for the [\*].

- Enforcement of Product Trademarks. Each Party shall notify the other Party in writing promptly upon learning of any actual or alleged infringement by any Third Party of any Product Trademark of which it becomes aware. The Trademark Owner shall have the first right, but not the obligation, to control the prosecution of any such infringement in consultation with and subject to oversight by the JCC. If the Trademark Owner does not initiate an infringement action within [\*] after learning of the infringement or within [\*] prior to any applicable deadline for taking action, then the other Party shall have the right, but not the obligation, to bring such an action in consultation with and subject to oversight by the JCC. In the case of a jointly-owned trademark, neither Party shall have the right to settle any infringement action under this Section 11.3.2 in a manner that diminishes the rights or interests of, or imposes any liability on, the other Party without the prior Party Written Consent of such other Party. The expenses of defense, settlement and judgments in actions governed by this Section 11.3.2 shall be [\*] (to the extent not reimbursed through recoveries from such litigation) to the extent related to the [\*] Markets, and shall be borne solely by [\*] to the extent related to the [\*]. The costs and expenses of the Party bringing suit under this Section 11.3.2 shall be reimbursed first out of any damages or other monetary awards recovered in favor of Genmab or SGI (if such recovery is less than the Parties' aggregate costs and expenses incurred in such action, such recovery shall be allocated between the Parties on a pro rata basis based on their relative costs and expenses incurred in such action). The Party that does not control the action or suit hereunder shall cooperate with the controlling Party in connection with such action or suit. Any damages or other monetary awards remaining after payment of the Parties' expenses shall be allocated between the Parties in the same proportion as they share in Net Profit/Net Loss hereunder to the extent related to the [\*] Markets, and shall be retained solely by [\*] to the extent related to the [\*].
- 11.4 <u>Domain Names</u>. Subject to <u>Section 11.2.1</u>, the Parties shall use a common domain name incorporating the same brand name for the Product worldwide. The Parties shall jointly select domain names and will coordinate filing and registering such names; *provided*, that all such registered domain names shall be owned solely by and registered in the name of one Party as provided in <u>Section 11.2.1</u>.
- 11.5 <u>No Implied Licenses</u>. No right or license under any Genmab Technology or SGI Technology or any Product Trademark or Other Mark is granted or shall be granted by implication as a result of the respective rights of the Parties under this Agreement. All such rights or licenses are or shall be granted only as expressly provided in this Agreement (or the Collaboration Agreement).
- 11.6 <u>Defense of Third Party Patent Claims</u>. Each Party shall notify the other Party promptly upon learning of any actual or alleged Patent infringement claim brought by a Third Party against a Party or any of its Affiliates with respect to activities conducted by such Party or its Affiliates for the Product hereunder (hereinafter "<u>Patent Infringement Claims</u>"). Upon learning of any Patent Infringement Claim, [\*] shall take all reasonable and appropriate steps to resolve the Patent Infringement Claim, and give reasonable consideration to the other Party's suggestions regarding such Patent Infringement Claim. All Out of Pocket Costs incurred in

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bringing, maintaining and prosecuting any action described in this <u>Section 11.6</u> (including for outside counsel) shall be (a) included in Patent Costs and included in the calculation of [\*]. The non-resolving Party shall cooperate with the resolving Party in connection with any Patent Infringement Claims and all Out of Pocket Costs incurred for outside counsel and other Out of Pocket Costs incurred by such Party in providing such cooperation shall be (i) included in Patent Costs and included in the calculation of [\*].

- **11.7** <u>Amendment of Collaboration Agreement IP Provisions</u>. For clarity, Article [\*] of the Collaboration Agreement remain in full force and effect, subject to the following amendments:
- **11.7.1** Section [\*] of the Collaboration Agreement is hereby amended and restated in its entirety as follows:
  - "[\*] Subject to the oversight of the JSC under Section [\*], Section [\*], Section [\*] and Section [\*], in the event [\*], each Party shall be responsible for and shall control the preparation, filing, prosecution, grant, maintenance and defense, of any patents and patent applications claiming [\*] owned solely by it in accordance with Section [\*] and [\*], prepare, file, prosecute and maintain such patent rights in good faith consistent with its customary patent policy and its reasonable business judgment."
- **11.7.2** Section [\*] of the Collaboration Agreement is hereby amended by inserting the following new Section [\*] after Section [\*]:
  - "[\*] Notwithstanding the foregoing, the Parties agree that pursuant to the potential Commercialization of the Collaboration Product known as "Tisotumab Vedotin," which is defined as the "Product" in the Joint Commercialization Agreement between the parties dated October 19, 2020 ("Tisotumab Vedotin"), all (a) patent applications and patents listed under [\*], and all patent applications and patents listed under [\*], (b) [\*], and (c) future patents issued from any such patent applications referred to in (a) or (b) above, and future patents issued from any continuation, continuation-in part [\*], or divisional of any of the foregoing patent applications or any patent applications from which the patents in (a) or (b) issued, in each case to the extent Controlled by [\*], and in each of (a) through (c) that are necessary or reasonably useful for the Development, manufacturing, or Commercialization of Tisotumab Vedotin (collectively, the [\*]), shall be treated as if they were [\*] pursuant to the procedures described in Section [\*]."
    - **11.7.3** Section [\*] of the Collaboration Agreement is hereby amended [\*] as follows:
    - "[\*] shall have the right, [\*], to determine the appropriate course of action to enforce patents claiming [\*] owned solely by [\*] in accordance with Section [\*] and the [\*] Patent Rights, or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the [\*] Patent Rights, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the [\*] Patent Rights. All monies recovered upon the final judgment or settlement of any such suit to enforce any [\*] Patent Rights shall be

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retained by [\*]. [\*] shall fully cooperate with [\*], in any action to enforce the [\*] Patent Rights.

Notwithstanding the foregoing, the following shall apply if enforcement of the [\*] Patent Rights arises in connection with a [\*]: The Parties shall, subject to oversight of the JSC under Section 3.2.2(f), jointly determine the appropriate course of action (i) to enforce [\*] and the [\*] Patent Rights or otherwise to abate the infringement thereof, (ii) to take (or refrain from taking) appropriate action to enforce the [\*] Patent Rights, (iii) to control any litigation or other enforcement action and (iv) to enter into, or permit, the settlement of any such litigation or other enforcement action for the [\*] Patent Rights, in each of (i) through (iv) with respect to a [\*]. The costs for any such actions shall be [\*]. All monies recovered upon the final judgment or settlement of any such suit to enforce any [\*] Patent Rights with respect to a [\*] shall be [\*]. Notwithstanding the foregoing, if the JSC cannot agree on enforcement of the [\*] Patent Rights, with respect to a [\*], the Party [\*] shall have final decision-making authority with respect to enforcement [\*].

In the case of an [\*], if [\*] fails to exercise its rights under this Section [\*] to take any action to enforce the [\*] Patent Rights or control any litigation with respect to the [\*] Patent Rights with respect to the manufacture, use or sale by Third Parties of [\*] within a period of [\*] after the Parties receive reasonable notice of the infringement of the [\*] Patent Rights, then [\*] shall have the right to bring and control any such action [\*], and permit the settlement of any such litigation or other enforcement action with respect to the [\*] Patent Rights, so long as this does not adversely affect [\*] rights under this Agreement. In such case, [\*] recovered upon the final judgment or settlement of any such suit to enforce any [\*] Patent Rights shall be [\*]. In such a case, [\*] shall cooperate fully with [\*], in its efforts to enforce the [\*] Patent Rights, including being joined as a party to such action if necessary. In no event may [\*] assert an argument or settle a suit in a manner which would render a claim in the [\*] Patent Rights invalid or unenforceable [\*]."

**11.7.4** Section [\*] of the Collaboration Agreement is hereby amended [\*] as

follows:

"[\*] shall have the right, [\*], to determine the appropriate course of action to enforce
[\*] ([\*] Patent Rights, and other than its interest in [\*]), or otherwise to abate the infringement thereof, to
take (or refrain from taking) appropriate action to enforce such [\*] Patents, to control any litigation or
other enforcement action and to enter into, or permit, the settlement of any such litigation or other
enforcement action with respect to such [\*] Patents."

- **11.8** Patent Costs. The Parties agree to handle Patent Costs for the Product under this Agreement such that SGI or Genmab [\*].
- **11.9** Court or Government Order or Decree. Notwithstanding any other provision in this Agreement, neither Party shall be required to take any action pursuant to this <u>ARTICLE 11</u> that it reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree or any agreement with any Governmental Authority that it is then subject to or otherwise may create legal liability on the part of it.

### **ARTICLE 12**

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#### AMENDMENT TO EXCLUSIVITY PROVISIONS OF COLLABORATION AGREEMENT

- **12.1** Overview. Without limiting any other amendments to the terms or conditions of the Collaboration Agreement that may be contained in this Agreement, the Parties agree that the Collaboration Agreement is hereby further amended as provided in this <u>ARTICLE 12</u>.
- **12.2** <u>Amendments to Section 1.1 of the Collaboration Agreement.</u> Section 1.1 of the Collaboration Agreement is hereby amended by inserting the following definitions following Section 1.1.132 thereof:
  - "1.1.133 "Acquired Party" has the meaning set forth in Section 3.4.4(a).
- 1.1.134 "Cease Activities for the Competing Product" has the meaning set forth in Section 3.4.3(ii).
  - 1.1.135 "Competing Party" has the meaning set forth in Section 3.4.3.
  - "Grace Period Activities" has the meaning set forth in Section 3.4.3(ii).
- 1.1.137 "**Divest**" means, with respect to a Competing Product, (a) the sale of all right, title and interest in such Competing Product, including all technology, intellectual property and other assets relating solely thereto, to a Third Party, without the retention or reservation of any rights, license or interest (other than solely an economic interest) by the selling entity or its Affiliates; or (b) the complete termination or withdrawal of such Competing Product, or shut-down of such development program for such Competing Product, such that no technology, intellectual property or other asset solely relating thereto is used by the terminating entity or its Affiliates. "Divestiture" shall have a correlative meaning.
  - 1.1.138 "**Divestment Period**" has the meaning set forth in Section 3.4.3(i).
  - "Genmab Sensitive Information" has the meaning set forth in Section 3.4.4(c).
- 1.1.140 "**Required Notice Date**" means, with respect to a Competing Product that a Competing Party obtains ownership, license, or other rights to as a result of a relevant transaction consummated by such Competing Party, [\*] days after the consummation thereof.
- 1.1.141 "Segregate" means, with respect to a Competing Product, to use diligent efforts to segregate, consistent with best industry practices, the research, development, manufacture and commercialization activities relating to such Competing Product from research, Development, Manufacture and Commercialization with respect to any Licensed Product under this Agreement (including for clarity the "Product" as defined under the Joint Commercialization Agreement entered into between the Parties dated October 19, 2020 (the "Commercialization Agreement")), including using diligent efforts to ensure that: (a) no personnel involved in performing the research, development, manufacture or commercialization of such Competing Product have access to [\*] (provided, that management personnel may [\*]); and (b) no personnel involved in performing the research, Development, Manufacture or Commercialization of any Licensed Product have access to [\*] (provided, that management personnel may [\*]).
  - 1.1.142 **"SGI Sensitive Information"** has the meaning set forth in Section

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3.4.4(b)."

**12.3** <u>Amendments to Section 3.4 of the Collaboration Agreement</u>. Section 3.4 of the Collaboration Agreement is hereby amended and restated in its entirety as follows:

#### "3.4 Exclusivity

- **3.4.1** Except as expressly set forth in this Agreement or the Commercialization Agreement, the Parties and their Affiliates shall work exclusively with each other to develop and commercialize Exclusive Products (for which the Opt-In Period has not yet expired) and Collaboration Products solely in accordance with the terms of this Agreement. Subject to the terms of this Agreement and the Commercialization Agreement, each Party shall be free to work alone or with Affiliates or Third Parties to research, develop, and commercialize any product that is not a Competing Product.
- **3.4.2** Except as expressly permitted in this Section 3.4, neither Party nor any of their respective Affiliates shall, directly or indirectly, perform research, conduct clinical development of, commercialize, or otherwise acquire rights to any Competing Product.
- **3.4.3** If a Party or any of its Affiliates, either as a result of an acquisition by such Party or its Affiliates of a Third Party or any of its business or assets, obtains ownership, license or other rights to a Competing Product (or, as a result of such acquisition, has as an Affiliate that has an ownership, license or other rights to a Competing Product), then such Party or its Affiliate (the "**Competing Party**") shall promptly notify the other Party in writing no later than the Required Notice Date that it is electing to:
- (i) Divest itself of such Competing Product via a transaction in which such Party and its Affiliates no longer has an economic interest in the future sales of the Competing Product and notify the other Party in writing of such Divestiture; *provided*, that such Divestiture must be completed prior to (x) the expiration of [\*] following the Required Notice Date in the case of a Competing Product that is [\*], and (y) at least [\*] prior to [\*], in the case of a Competing Product that is [\*] (the "**Divestment Period**"); or
- (ii) (A) commit not to, and to cause its Affiliates not to, directly or indirectly, by itself or with a Third Party, market, promote, sell, manufacture or distribute for commercial sale such Competing Product, or (B) in the case of any such Competing Product with respect to which [\*], cease engaging in such prohibited activities with respect to such Competing Product (in which event the Competing Party shall have a period of [\*] after the Required Notice Date to sell off existing inventory or work-in-progress of the Competing Product) (the "Grace Period Activities") ((A) and (B) collectively, "Cease Activities for the Competing Product").

If the Competing Party notifies the other Party that it elects to Cease Activities for the Competing Product as set forth hereunder, the Competing Party shall immediately start to Cease Activities for the Competing Product. For clarity, if the Parties mutually agree in writing to an alternative arrangement (such as bringing the Competing Product under this Agreement or transitioning the Competing Party to a passive role hereunder), the Competing Party shall not be in breach of Section 3.4 to the extent it carries out the mutually agreed alternative arrangement. Moreover, in circumstances where the Competing Party notifies the other Party that it intends to Divest the Competing Product pursuant to Section 3.4.3(i) and fails despite using Commercially Reasonable Efforts to complete such

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Divestiture within the Divestment Period, the Competing Party shall not be in breach of this Section 3.4 if it Ceases Activities for the Competing Product after the end of the Divestment Period (*provided*, that in such circumstance the Competing Party shall have no further right to conduct the Grace Period Activities).

### 3.4.4 Change of Control

- (a) Notwithstanding anything to the contrary herein, any intellectual property Controlled by any Person that becomes an Affiliate of a Party (the "Acquired Party") as a result of a Change of Control of such Acquired Party or its Affiliate shall not be Genmab Technology or SGI Technology, as applicable, unless (i) such technology or rights had been Controlled, prior to the Change of Control, by such Acquired Party or its Affiliate(s) that were Affiliate(s) prior to the Change of Control or (ii) with respect to any of the foregoing technology covered by patent rights, at least one named inventor was employed by such Acquired Party or its then Affiliate(s) immediately prior to the public announcement of the transaction(s) giving rise to such Change of Control.
- (b) Following any Change of Control of Genmab or its Affiliates, in the event the applicable acquirer has, or has rights or an interest in, at the time of the Change of Control, a Competing Product, Genmab shall be required to, and shall cause its Affiliates to: (i) Segregate such Competing Product and (ii) establish reasonable firewalls to prevent disclosure of non-public plans or non- public information relating to the Development, Manufacturing or Commercialization of any Licensed Product or any Confidential Information of SGI (collectively, the "SGI Sensitive Information") beyond personnel of Genmab or its Affiliates who continue to actively perform obligations under this Agreement, and to prevent the dissemination of SGI Sensitive Information disclosed after the Change of Control of Genmab or its Affiliates to such acquirer or its Affiliates. For clarity, the foregoing will not apply to any SGI Sensitive Information that is not Confidential Information under Section 13.1 or "Confidential Information" (as such term is defined under the Commercialization Agreement). Notwithstanding the foregoing, following such Change of Control of Genmab or its Affiliates, Genmab will be allowed to provide information regarding the amount of financial payments (including the underlying reports provided hereunder) from SGI to Genmab hereunder to such acquirer or its Affiliates.
- (c) Following any Change of Control of SGI or its Affiliates, in the event the applicable acquirer has, or has rights or an interest in, at the time of the Change of Control, a Competing Product, SGI shall be required to, and shall cause its Affiliates to (i) Segregate such Competing Product and (ii) establish reasonable firewalls to prevent disclosure of non-public plans or non-public information relating to the Development or Commercialization of any Licensed Product or any Confidential Information of Genmab (collectively, the "Genmab Sensitive Information") beyond personnel of SGI or its Affiliates who continue to actively perform obligations under this Agreement, and to prevent the dissemination of Genmab Sensitive Information disclosed after the Change of Control of SGI or its Affiliates to such acquirer or its Affiliates. For clarity, the foregoing will not apply to any Genmab Sensitive Information that is not Confidential Information under Section 13.1 or "Confidential Information" (as such term is defined under the Commercialization Agreement). Notwithstanding the foregoing, following such Change of Control of SGI or its Affiliates, SGI will be allowed to provide the information regarding the amount of financial payments

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(including the underlying reports provided hereunder) from Genmab to SGI hereunder to such acquirer or its Affiliates.

- **3.4.5** In the period either prior to SGI's first Opt-In Notice or after any relevant Opt-Out Date, Genmab may use antibody-drug conjugates targeted to Tissue Factor, including ADCs, in studies designed to evaluate, research, develop or commercialize an antibody-drug conjugate with a target other than Tissue Factor; <u>provided</u>, that such studies are non-clinical in nature. At any other time during the Term, neither Party may use antibody-drug conjugates targeted to Tissue Factor in such studies without the prior written consent of the other Party, such consent not to be unreasonably withheld. The Parties agree that any ongoing activities initiated prior to SGI's first Opt-In Notice may be finalized according to the contemplated plan.
- **3.4.6** Notwithstanding anything to the contrary in this Agreement, Genmab shall be permitted to develop and commercialize, alone or with a partner, a [\*] with specificity against Tissue Factor for diagnostic purposes. Genmab shall ensure that any agreements with Third Parties pertaining to the development, commercialization or licensing of such products contain provisions permitting the Parties to use such products to support the development and commercialization of Licensed Products, if appropriate. At any time during the Term, Genmab shall be permitted to use a [\*] with specificity against Tissue Factor for research purposes. Following an Opt-Out Notice by SGI or if SGI does not exercise its Opt-In Right for the first Exclusive Product, Genmab shall be permitted to develop, alone or with a partner, a [\*] with specificity against Tissue Factor for any purpose. Following an Opt-Out Notice by SGI or if SGI does not exercise its Opt-In Right for the first Exclusive Product, Genmab shall, alone or with a partner, be permitted to commercialize such [\*] with specificity against Tissue Factor for any purpose after [\*] of the date of First Commercial Sale in a Major Market Country of an Exclusive Product or Genmab Product."

#### ARTICLE 13 CONFIDENTIALITY

#### **13.1** Confidentiality.

means all Information, documents (including unpublished patent applications), trade secrets, or materials supplied by the other Party or any of its Affiliates (the "Disclosing Party") under this Agreement, whether disclosed orally, visually, in writing or in any tangible or electronic form or media, that is confidential or proprietary and is marked or otherwise identified as "Confidential" or which the receiving Party or any of its Affiliates (the "Receiving Party") should reasonably recognize as being confidential. Confidential Information may be owned by the Disclosing Party or held by the Disclosing Party under an obligation of confidentiality to a Third Party. The terms of this Agreement and Information related directly to the Product shall be the Confidential Information of both Parties; provided, that Drug Conjugation Technology (as such term is defined in the Collaboration Agreement) will be Confidential Information of SGI. Confidential Information of a Party may also include information relating to such Party's or its Affiliates' research programs, development, marketing, manufacturing, regulatory matters, business practices and finances. Information shall not be considered Confidential Information to the extent that such Information:

(a) has been published or otherwise entered the public domain other than by breach by the Receiving Party of this <u>ARTICLE 13</u> or directly or indirectly under any other agreement between the Parties that imposed obligations of confidentiality;

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- **(b)** has been disclosed to the Receiving Party by a Third Party that is not breaching any duty of confidentiality by disclosing the same; *provided*, that such Information was not obtained by such Third Party directly or indirectly from the Disclosing Party on a confidential basis;
- **(c)** prior to disclosure by the Disclosing Party under this Agreement, the Collaboration Agreement or directly or indirectly under another agreement between the Parties that imposed obligations of confidentiality, was already in the possession of the Receiving Party, as demonstrated by the Receiving Party by competent written evidence; or
- **(d)** was developed independently of and without reference to the Disclosing Party's Confidential Information, as demonstrated by the Receiving Party by competent written evidence.
- 13.1.2 Non-Disclosure Obligations. Except as otherwise provided in this ARTICLE 13, during the Term and for a period of [\*] thereafter, each Party shall maintain in confidence, and use only for purposes as expressly authorized and contemplated by this Agreement, all Confidential Information supplied by or on behalf of the other Party or its Affiliates under this Agreement. Each Party shall use at least reasonable care, and in no event less than the same standard of care as it uses to protect its own Confidential Information, to ensure that its and its Affiliates' employees, agents, consultants and clinical investigators only make use of the other Party's or its Affiliates' Confidential Information for purposes as expressly authorized and contemplated by this Agreement or the Collaboration Agreement and do not make any unauthorized use or disclosures of such Confidential Information.
- **13.1.3** <u>Permitted Disclosures</u>. Notwithstanding <u>Section 13.1.2</u>, Confidential Information may be disclosed by the Receiving Party solely to the extent such Confidential Information:
  - (a) is permitted to be disclosed by prior written consent of the other Party;
- **(b)** is disclosed in the filing, prosecution or maintenance of patents solely in accordance with this Agreement or the Collaboration Agreement, *provided*, that (i) such disclosure may be only to the extent reasonably necessary for such purpose and (ii) the Receiving Party complies with the obligations set forth in Section 13.1.2;
- **(c)** is disclosed to a Regulatory Authority in accordance with this Agreement or as required by the Applicable Law to obtain or maintain a Regulatory Approval; *provided*, that such disclosure may be only to the extent reasonably necessary for such purpose;
- **(d)** is deemed necessary by the Receiving Party to be disclosed to such Party's financial advisors, attorneys or independent accountants for the sole purpose of enabling such financial advisors, attorneys or independent accountants to provide professional advice to the Receiving Party; *provided*, that such Third Parties are bound by confidentiality and non-use obligations customary for the type of professional and are advised that the information being disclosed is confidential;
- **(e)** is deemed necessary by the Receiving Party to be disclosed to accredited investors, lenders or bona fide potential acquirers or merger candidates in the context of due diligence investigations of such Party solely for the purpose of evaluating a potential business relationship; *provided*, that such Third Parties are bound by confidentiality and non-use obligations (i) customary for the type of

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recipient in the case of all recipients who are not potential acquirers or merger candidates, and (ii) contained in this Agreement, in the case of potential acquirers or merger candidates, but in no event pursuant to (i) or (ii) for a term of less than ten (10) years, and are advised that the information being disclosed is confidential;

- (f) is deemed necessary by the Receiving Party to be disclosed to such potential Third Party(ies) for a Commercial License or Third Party License Agreement as permitted hereunder; *provided*, that any such potential Third Party is bound by obligations of confidentiality and limitations on use of such Confidential Information contained herein;
- **(g)** is disclosed to a potential or bona fide collaborator or manufacturing, development or sales contractor or partner (including any Approved Subcontractor) but only to the extent directly relevant to the collaboration, contract or partnership;

*provided*, that such collaborator, contractor or partner is bound by obligations of confidentiality and limitations on use of such Confidential Information contained herein; or

**(h)** is disclosed in accordance with <u>Section 13.1.4</u>.

Notwithstanding the disclosures permitted under subsections (a)-(h), such Confidential Information shall remain otherwise subject to the non-disclosure and non-use provisions of this <u>ARTICLE 13</u>.

- Applicable Law or the rules of any Securities Exchange to disclose Confidential Information of the other Party or any of its Affiliates, the Party being compelled shall (if not prohibited by Applicable Law from doing so) promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Without limiting Section 13.1.3, each Party agrees that it shall cooperate fully and in a timely manner with the other Party with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies or Securities Exchanges, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure.
  - **13.2** <u>Publicity</u>. Neither SGI nor Genmab will, without the prior written consent of the other Party, issue any press release or make any other public announcement or furnish any statement to any Person (other than either Parties' respective Affiliates) concerning the existence of this Agreement, its terms and the transactions contemplated hereby, except for disclosures made in compliance with <u>ARTICLE 13</u>.
  - 13.3 Securities Filings. In the event either Party proposes to file with the U.S. Securities and Exchange Commission or the securities regulators of any state or other jurisdiction under the Securities Act of 1933, the Exchange Act, or any other applicable securities law (the "Securities Exchanges") a registration statement or any other disclosure document which describes or refers to this Agreement, such Party shall notify the other Party of such intention and shall provide the other Party with a copy of relevant portions of the proposed filing not less than [\*] Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to this Agreement, and shall use reasonable efforts to obtain confidential treatment of this Agreement that the other Party requests be kept confidential, consistent with such Party's disclosure obligations under applicable securities laws.
  - **13.4** <u>Publications</u>. Except as otherwise permitted pursuant to this <u>ARTICLE 13</u>, neither Party may publish, present or announce results of the Development of the Product either orally or in writing (a

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"Publication") without complying with the provisions of this Section 13.4. The other Party shall have [\*] days from receipt of a proposed Publication to provide comments or proposed changes to the publishing Party. The publishing Party shall take into account the comments or proposed changes made by the other Party on any Publication and shall agree to designate employees or others acting on behalf of the other Party as co-authors on any Publication describing results to which such persons have contributed in accordance with standards applicable to authorship of scientific publications. If the other Party reasonably determines that the Publication would entail the public disclosure of such Party's Confidential Information or of a patentable invention, submission of the concerned Publication to Third Parties shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the other Party (if the other Party has requested deletion thereof from the proposed Publication) or the drafting and filing of a patent application covering such invention; provided, such additional period shall not exceed [\*] days from the date the publishing Party first provided the proposed Publication to the other Party. In addition, any publications or presentations in any medium with respect to the Product or activities under this Agreement must comply with the publications charter agreed by the Parties under the Collaboration Agreement, as such charter may be updated or amended by the JMAT from time to time consistent with this Section 13.4 and the other terms and conditions of this Agreement (the "Publication Charter"). As amended, such Publication Charter shall apply to the Product, only, and not to any other Licensed Product under the Collaboration Agreement. In the event of a conflict between the terms of the Publication Charter and the terms of this Agreement, the terms of this Agreement shall prevail.

13.5 Existing Confidentiality Agreement. The Parties acknowledge that Article 13 of the Collaboration Agreement contains confidentiality and non-use provisions that shall remain in full force and effect solely with respect to information not related to the Product and the confidentiality provisions in this Agreement shall govern all information related to the Product from and after the Effective Date. Notwithstanding the foregoing, in the event of any conflict between the terms of Article 13 of the Collaboration Agreement and the terms of this Agreement, the terms of this Agreement shall control with respect to the matters related to the Product.

#### **ARTICLE 14 TERM AND TERMINATION**

- **14.1** <u>Term</u>. The term of this Agreement (the "<u>Term</u>") shall become effective on the Effective Date and shall remain in effect until expired or terminated as provided in this <u>ARTICLE 14</u>.
- **14.2** Expiration. This Agreement shall expire on country-by-country basis, on the date of complete and permanent cessation of Development, Commercialization and any other sale of Product in or for such country. For clarity, this Agreement shall expire in its entirety upon complete and permanent cessation of Development, Commercialization and any other sale of Product in all countries in the Territory. Upon expiration of this Agreement with respect to a country, the Collaboration Agreement will automatically terminate with respect to the Product with respect to such country, and neither Party shall Develop, Commercialize or otherwise sell the Product in or for the relevant country without the prior written agreement of the other Party.

#### 14.3 Material Breach.

**14.3.1** <u>Breach.</u> If either Party (the "<u>Non-Breaching Party</u>") believes that the other Party (the "<u>Breaching Party</u>") has materially breached its obligations under this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a "<u>Default Notice</u>"). Such Default Notice may include an allegation from the Non-Breaching

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Party that the alleged material breach by the Breaching Party [\*] (a "Fundamental Breach") or is a material breach of the Agreement affecting only (a) [\*], (b) [\*], (c) [\*], or (d) [\*] (each of (a) through (d), an "Affected Region" and the material breach with respect to such Affected Region, a "Regional Material Breach"). For clarity, it is possible that a material breach of this Agreement by a Party with respect to one or more countries may constitute a Fundamental Breach of this Agreement if the relevant material breach fundamentally frustrates the purpose of the Agreement as a whole. If the Breaching Party does not dispute that it has materially breached its obligations under this Agreement, then if the Breaching Party fails to cure such breach within [\*] days after receipt of the Default Notice, or if such cure cannot reasonably be fully achieved within such [\*] period and the Breaching Party has failed to commence curing such breach using diligent efforts to cure such breach as soon as reasonably practicable (not to exceed a total of [\*] additional days), then, Section 14.3.2 shall apply. If a cure cannot reasonably be fully achieved within [\*] days of receipt of a Default Notice and the Breaching Party has commenced using diligent efforts to cure such breach in accordance with this <u>Section 14.3.1</u>, <u>Section 14.3.2</u> shall not apply for such time as is reasonably necessary to fully achieve the relevant cure so long as the Breaching Party is using diligent efforts to cure such breach; provided, that in no event shall the cure period extend for more than [\*] after the date upon which the breaching Party receives the notice of such material breach from the other Party. If the Breaching Party disputes that it has (i) materially breached its obligations under this Agreement, (ii) failed to cure such breach, or (iii) failed to commence curing such breach using diligent efforts to cure such breach as provided in this Section 14.3.1, in each case, such dispute shall be resolved in accordance with ARTICLE 16. If, as a result of the application of such arbitration procedures, the Breaching Party is determined to be in material breach of its obligations under this Agreement (including, if applicable, a Fundamental Breach or a Regional Material Breach) and has failed to cure such breach within the foregoing time period as applicable (an "Adverse Ruling"), then, if the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within [\*] after such ruling, or if such compliance cannot be fully achieved within such [\*] and the Breaching Party has failed to commence compliance or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, then <u>Section 14.3.2</u> shall apply. During the pendency of any such dispute, all rights, remedies and cure periods relating to the dispute and any alleged breach shall be tolled, and all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

#### 14.3.2 Non-Breaching Party Right.

written notice by the Non-Breaching Party, the Breaching Party will be deemed to have provided an Opt-Out Notice for the Product for purposes of Section 5.10 of the Collaboration Agreement and Sections 5.10.3 and 5.10.4 of the Collaboration Agreement shall apply. If a Fundamental Breach occurs and the Non-Breaching Party exercises its rights pursuant to Section 14.3.1 with respect thereto, then the second, third and fourth sentences of Section 5.10.3 of the Collaboration Agreement shall not apply, but instead the remainder of this Section 14.3.2(a) shall apply: The Breaching Party will not be refunded or repaid any amounts it has paid for the Development or Commercialization of the Product. In addition, the Breaching Party will remain responsible for its share of Development Costs and Allowable Expenses incurred with respect to the Product through [\*] following the date of the Non-Breaching Party's exercise of its rights pursuant to this Section 14.3.2(a), to the extent such costs and expenses were incurred pursuant to applicable Approved Plans. Furthermore, for [\*] after the date of such termination, the Breaching Party shall provide development, consultation or support work for the Product, as reasonably requested by the Non-Breaching Party, and the Non-Breaching Party shall reimburse the Breaching Party's FTE Costs for such work at the annual rate per FTE as in force between the Parties at such date.

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- written notice by the Non-Breaching Party, the Affected Region(s) shall be deemed part of (i) if Genmab is the Non-Breaching Party, the "Genmab Royalty Territory" (operating mutatis mutandis as if such Affected Region(s) were included in the Royalty Territory except that Genmab would have the rights and obligations as if Genmab were SGI under this Agreement with respect to the Product in the Affected Region) for all purposes under this Agreement (and shall no longer be a Genmab Major Market, SGI's Major Market(s) or Royalty Territory, as applicable), and (ii) if SGI is the Non-Breaching Party, the Royalty Territory for all purposes under this Agreement (and shall no longer be Genmab's Major Market or SGI's Major Market(s)) and shall be treated in the same manner as any other countries in the Royalty Territory; provided, however, that in each of (i) and (ii), as applicable, all amounts otherwise payable to the Breaching Party with respect to Net Sales of the Product in the Affected Region that would apply pursuant to Section 5.2 shall be reduced by [\*]; provided, further, that in no event shall the royalty rates set forth in Section 5.2.1 be reduced pursuant to Section 5.2.2, Section 5.2.3 and this Section 14.3.2(b) by more than [\*], in the aggregate.
- (c) If the Non-Breaching Party exercises its rights pursuant to <u>Section 14.3.2(b)</u>, then promptly thereafter, the Parties will work together to and complete a transfer and assignment to the Non-Breaching Party of all regulatory documents, contracts, licenses, collaborations, materials and information that are reasonably necessary for the Non-Breaching Party to exercise such rights, which transfer and assignment shall be at the Breaching Party's sole cost and expense (which shall include the FTE Costs and Out of Pocket Costs incurred by the Non-Breaching Party to effect such transfer and assignment). In such case, the Breaching Party shall use Commercially Reasonable Efforts to transition all activities to be transferred or assigned to the Non-Breaching Party pursuant to this <u>Section 14.3.2(c)</u> as promptly as practicable.
- (d) No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law or equity. Without limiting Section 14.3.1 or ARTICLE 16, in addition to the other rights of the Non-Breaching Party under this Section 14.3.2, the Non-Breaching Party may offset against amounts payable to the Breaching Party pursuant to this Agreement any damages resulting from such material breach.
- **14.3.3** <u>No Termination</u>. For clarity, unless otherwise expressly set forth in <u>Section 14.3.2</u>, the Parties agree that this Agreement will not be terminated pursuant to this <u>Section 14.3</u> and the Breaching Party shall continue to be obligated to perform any activities not assumed by the Non-Breaching Party pursuant to <u>Section 14.3.2</u> and shall continue to share in Net Profit/Net Loss or receive or pay royalties with respect to the Royalty Territory, as applicable, as set forth in this Agreement (subject to any adjustment made pursuant to <u>Section 14.3.2</u> or as a result of dispute resolution hereunder).
- 14.4 Termination of Co-Funding; Out-License of Product. For clarity, Section 5.10 of the Collaboration Agreement continues to apply to the Product; *provided*, the Opt-Out Date for the Product will be effective [\*] after the Non-Continuing Party provides written notice to the other Party (such notice being irrevocable once provided), and the Continuing Party shall have the right to determine whether it will assume sole responsibility for Development and Commercialization of the Product. If the Continuing Party so elects, then, on and after the effective date of termination, the Product shall be treated as a Genmab Product (if Genmab is the Continuing Party) or an SGI Product (if SGI is the Continuing Party) and the terms of the Collaboration Agreement shall apply with respect to Product (including Section 5.10 of the Collaboration Agreement and the payment of royalties and milestones pursuant to Article 10 of the Collaboration Agreement).
  - **14.5** <u>Termination for Insolvency; Bankruptcy.</u> Either Party may terminate this Agreement if, at any

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time, the other Party (a) shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) proposes a written agreement of composition or extension of its debts, (c) shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within [\*] days after the filing thereof, (d) shall propose or be a party to any dissolution or liquidation, or (e) shall make an assignment for the benefit of its creditors. Notwithstanding the foregoing, the Parties intend for this Agreement and the licenses granted herein to come within Section 365(a) of the United States Bankruptcy Code, and notwithstanding the bankruptcy or insolvency of SGI, this Agreement and the licenses granted herein shall remain in full force and effect so long as Genmab shall remain in material compliance with the terms and conditions hereof.

- **14.6** Remedies. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one (1) or more countries or other jurisdiction(s)) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.
- Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, ARTICLE 1 (to the extent defined terms are used in any other surviving provisions), the first sentence of Section 3.7.5, Section 3.7.6, Section 4.5, Section 5.7 (and with respect to amounts owed or rights accrued prior to termination or expiration of this Agreement, Sections 5.1-5.6), Section 8.1.2, the last sentence of Section 10.2, Section 10.3, Section 11.1, Section 11.2 (with respect to ownership of Product Trademarks and use of Other Marks), Section 11.5, Section 11.7, ARTICLE 12, ARTICLE 13, this ARTICLE 14, ARTICLE 15, ARTICLE 16 and <u>ARTICLE 17</u> of this Agreement shall survive the termination or expiration of this Agreement for any reason. For the avoidance of doubt, (a) the license granted by Genmab to SGI under Section 2.4.2 of the Collaboration Agreement with respect to the Product is subject to the terms and conditions of this Agreement in all respects, including with respect to the payment of royalties hereunder during the Royalty Term on a country-by-country basis, (b) such license with respect to the Product for the Royalty Territory shall survive the expiration of the Royalty Term under this Agreement on a country-by-country basis as a royalty-free, fully paid-up license, and (c) references to the "Commercialization Plan" in Section 2.4.2 of the Collaboration Agreement shall be deemed to be references to this Agreement. For the further avoidance of doubt, (i) the license granted by SGI to Genmab under Section 2.1.2 of the Collaboration Agreement with respect to the Product is subject to the terms and conditions of this Agreement in all respects, including (in the event that one or more Affected Region(s) have been deemed part of the Genmab Royalty Territory pursuant to Section 14.3.2(b)) with respect to the payment of royalties hereunder during the Royalty Term on a country-by-country basis, (ii) such license with respect to the Product for the Genmab Royalty Territory shall survive the expiration of the Genmab Royalty Term under this Agreement on a country-by-country basis as a royalty-free, fully paid-up license, and (iii) references to the "Commercialization Plan" in Section 2.1.2 of the Collaboration Agreement shall be deemed to be references to this Agreement.

#### **ARTICLE 15 INDEMNIFICATION**

**15.1** <u>Indemnification</u>. Subject to <u>Section 15.3</u>, each Party shall defend, indemnify and hold harmless the other Party, its Affiliates and their respective directors, officers, employees and agents (collectively, such Party's "<u>Indemnitees</u>") from and against all liabilities, losses, damages, and expenses, including reasonable attorneys' fees and costs (collectively, "<u>Losses</u>"), resulting from all Third Party claims, suits, actions, or

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demands (collectively, the "<u>Claims</u>") to the extent that such Losses are incurred, relate to or arise out of (a) the material breach of any provision of this Agreement or any other agreement between the Parties with respect to the Product by the indemnifying Party or its Affiliate (or the inaccuracy of any representation or warranty made by such Party in this Agreement), (b) the gross negligence, recklessness or willful misconduct of the indemnifying Party or its Affiliate in connection with the exercise of its rights or the performance of its obligations under this Agreement, or (c) solely with respect to SGI as the indemnifying Party, SGI's Development, Manufacturing, and Commercialization of the Product in the Royalty Territory.

#### **15.2** <u>Indemnification Procedure</u>.

- 15.2.1 A Party believing that it or its Indemnitees are entitled to indemnification under <u>Section 15.1</u> (an "<u>Indemnified Party</u>") shall give prompt written notification to the other Party (the "<u>Indemnifying Party</u>") of the commencement of any Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Claim as provided in this <u>Section 15.2</u> shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually materially prejudiced as a result of such failure to give notice). Subject to any written agreement by the Parties to the contrary, within [\*] after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If a Party believes that a Claim presented to it for indemnification is one as to which the Party seeking indemnification is not entitled to indemnification under <u>Section 15.1</u>, it shall so notify the Party seeking indemnification.
- 15.2.2 If the Indemnifying Party elects to assume the defense of such Claim, the Indemnified Party may participate in such defense with its own counsel, with the fees and expenses to be paid by the Indemnified Party, unless the representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual differing interests between such Indemnified Party and any other party represented by such counsel in such proceedings, in which case the reasonable fees and expenses of such counsel shall be paid by the Indemnifying Party.
- **15.2.3** In any event, the Indemnifying Party shall keep the other Party reasonably apprised of the status of such Claim and the defense thereof (including by providing copies of pleadings and such other documents, information, and correspondence reasonably requested by the Indemnified Party) and shall consider in good faith recommendations made by the Indemnified Party with respect thereto.
- 15.2.4 The Indemnified Party shall not agree to any settlement of such Claim without the prior Party Written Consent of the Indemnifying Party. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party or adversely affects the Indemnified Party without the prior Party Written Consent of the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed.
- **15.3** <u>Treatment of Manufacturing Losses</u>. Notwithstanding anything to the contrary contained in this Agreement or the Collaboration Agreement, the Parties agree to share equally in that portion of Manufacturing Losses that is included as Allowable Expenses or Development Costs hereunder.
- 15.4 <u>No Consequential or Punitive Damages.</u> EXCEPT (A) FOR WILLFUL MISCONDUCT, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER <u>ARTICLE 13</u>, AND (C) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM

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FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS <u>ARTICLE 15</u> OR UNDER ANY RELATED MANUFACTURING AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR ANY RELATED MANUFACTURING AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY OR THE USE OF THE PRODUCT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

**15.5** Effect on Collaboration Agreement. For clarity, the provisions of this ARTICLE 15 shall supersede the provisions of Section 18.2 of the Collaboration Agreement with respect to any right to indemnification by either Party for Claims to the extent that such Claims relate to or arise out of this Agreement or the performance of obligations under this Agreement with respect to the Product.

#### **ARTICLE 16 DISPUTE RESOLUTION**

**16.1** Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to decisions to be made by one or more of the Committees provided for herein or to the Party's respective rights or obligations hereunder. It is the desire of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to arbitration or litigation. To accomplish this objective, the Parties agree that, except for disputes regarding Party Tactical Matters or other matters for which a Party has final decision-making authority hereunder or as otherwise expressly provided in this Agreement, the dispute resolution procedures set forth in Section 23.3 of the Collaboration Agreement shall apply if and when a dispute arises under this Agreement; provided, that if such dispute is regarding a matter to be decided or agreed upon by a Committee as set forth herein, then the terms of Section 2.10.5 or Section 3.5.2, as applicable, shall first apply. For clarity, any dispute as to whether or not a matter (a) is a Party Tactical Matter, (b) requires Joint Committee Consent, (c) is a matter to which Section 2.10.5 applies, or (d) is subject to a Party's final decision-making authority hereunder shall be resolved, in each case ((a) through (d)), in accordance with this Section 23.3 of the Collaboration Agreement; except, that with respect to all dispute resolution procedures for matters hereunder to be resolved in accordance with Section 23.1 of the Collaboration Agreement, notwithstanding any provision in Section 23.1 of the Collaboration Agreement to the contrary, (i) the Parties agree that they will not challenge the jurisdiction or authority of the arbitration panel to decide the dispute or the arbitrability or admissibility of the relevant dispute and (ii) any dispute submitted to the arbitrator(s) that fell within the decision-making responsibilities of any Committee, Team, or Working Group in accordance with the terms of this Agreement, the arbitrator(s) must render their decision applying the substantive law of the state of New York and based on the principles of maximizing the value and reasonable commercial potential of the Product.

#### **ARTICLE 17 MISCELLANEOUS**

**17.1** [\*]. To the extent permissible under Applicable Law, each Party agrees that, during the Term, neither it nor any of its Affiliates that participates in or is responsible for activities for the Product pursuant to this Agreement shall [\*] conducted by the other Party or any of its Affiliates under this Agreement [\*] with such other Party or Affiliate and [\*]. For purposes of the foregoing, [\*]. This Section 17.1 shall not

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restrict either Party or any of its Affiliates from [\*] or [\*].

- Maintenance of Records. Each Party shall, and shall require its Affiliates to, and shall use Commercially Reasonable Efforts to cause its permitted sublicensees and Approved Subcontractors to, keep and maintain accurate and complete records of activities performed by or on behalf of such Party or any of its Affiliates, permitted sublicensees and Approved Subcontractors in connection with its or their activities under this Agreement (including records for Patent purposes), as well as all records required by Applicable Law with respect to the Product, and shall make copies of such records available to the other Party upon request. The Parties' and their Affiliates' obligations under this Section 17.2 shall continue for the longer of (a) five (5) years following the activity with respect to which the applicable records relate and (b) any applicable time period under Applicable Law.
- Force Majeure. No Party (or any of its Affiliates) shall be held liable or responsible to the other Party (or any of its Affiliates), or be deemed to have defaulted under or breached the Agreement, for failure or delay by such Party (or any of its Affiliates) in fulfilling or performing any term of the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (or any of its Affiliates), including fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, epidemics, pandemics, riots, civil commotions, acts of God, earthquakes, or omissions or delays in acting by any Governmental Authority ("Force Majeure"); provided, however, that the affected Party shall (a) promptly notify the other Party in writing of the existence of the Force Majeure, and (b) exert all Commercially Reasonable Efforts to eliminate, cure or overcome any such Force Majeure and to resume performance hereunder promptly. Notwithstanding the foregoing, to the extent that an event of Force Majeure continues for a period in excess of [\*], the affected Party shall promptly notify in writing the other Party of such continued event of Force Majeure and the Parties shall negotiate in good faith (i) a resolution of the event of Force Majeure, if possible, (ii) an extension by mutual agreement of the time period to resolve, eliminate, cure, or overcome such Force Majeure, (iii) an amendment of this Agreement to the extent reasonably possible, or (iv) an early termination of this Agreement. If the Parties do not reach such resolution within an additional [\*] period (or such period is not extended by mutual agreement of the Parties), the non-affected Party may terminate this Agreement on [\*] days advance written notice to the other Party. This Section 17.3 supersedes Section 19.1 of the Collaboration Agreement with respect to the Product.
- Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned, transferred or delegated to any Third Party by either Party without the consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; provided, however, that either Party may, without such consent but with notification, assign this Agreement and its rights and obligations hereunder [\*]. Any permitted assignee shall assume all rights and obligations of its assignor under this Agreement. Any attempted assignment of this Agreement not in accordance with this Section 17.4 shall be void and of no effect. This Agreement shall be binding on, and inure to the benefit of, each Party, its successors and permitted assigns. This Section 17.4 expressly supersedes Section 20.1 of the Collaboration Agreement and shall apply mutatis mutandis with respect to the assignability of the Collaboration Agreement. Additionally, this Agreement may only be assigned together with the Collaboration Agreement (in its entirety or in its entirety with respect to the Product) may only be assigned together with this Agreement.
- 17.5 <u>Severability.</u> Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual Party Written Consent, valid

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provisions for such invalid provisions, in their economic effect, are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement based on such valid provisions. In case such alternative provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

- **17.6** <u>Insurance</u>. The insurance provisions of Article 22 of the Collaboration Agreement shall apply to the activities conducted hereunder.
- 17.7 <u>Notices</u>. All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when: (a) delivered in person; or (b) delivered by first class air mail or internationally recognized courier service, postage prepaid, addressed to the other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the address to the other Party in accordance with this <u>Section 17.7</u>. For clarity, this <u>Section 17.7</u> is not intended to apply to day-to-day business communications made in the ordinary course.

For Genmab:

Genmab A/S

Attention: Head of Legal Email: [\*]

the address of Genmab as registered in the Danish Central Business Register (or any successors hereof)

or

the address of Genmab as registered at the Genmab's official homepage (currently www.genmab.com)

Invoices to Genmab: [\*]

For SGI:

Seagen Inc.

21823 30th Drive S.E. Bothell, WA 98021 Telephone: +1 (425) 527-4000 Facsimile: [\*]

Email: [\*]

Attention: General Counsel

With copies of invoices to:

Accounts Payable 21823 – 30th

Drive SE

Bothell, WA 98021 Email: [\*]

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

**17.8** Governing Law. The Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of law principles thereof that may dictate application of the laws of any other state or the United States.

#### 17.9 Headings; Construction.

- 17.9.1 Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between each of them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- 17.9.2 The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include," "includes" and "including," the phrase "for example" and the abbreviation "e.g.," shall each be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." The word "any" shall mean "any and all" unless otherwise clearly indicated by context. The word "or" is used in the inclusive sense (and/or) unless the context otherwise requires.
- 17.9.3 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Applicable Law herein shall be construed as referring to such Applicable Law as from time to time enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and permitted assigns, (d) the words "herein," "hereof" and "hereunder," and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) references to "drugs" or pharmaceutical products or therapies include biological products or therapies, and (f) all references herein to Articles, Sections or Schedules, unless otherwise specifically provided, shall be construed to refer to Articles, Sections and Schedules of this Agreement. As used herein, the reference to an Article refers to all of the Sections under that Article.
- **17.9.4** The headings of Articles and Sections of this Agreement are for ease of reference only and shall not affect the meaning or interpretation of this Agreement in any way.
- **17.10** <u>No Third Party Beneficiaries</u>. No Person other than Genmab, SGI and their respective Affiliates, successors and permitted assignees hereunder, shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.
- 17.11 <u>Entire Agreement; Amendment</u>. This Agreement, together with the Schedules hereto, the Collaboration Agreement and the supply agreements, quality agreements, and pharmacovigilance agreements referenced herein, together with the exhibits and schedules thereto, contains the entire understanding of the Parties with respect to the specific subject matter hereof. All other express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded. This

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Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

## 17.12 <u>Relationship Between Agreements</u>.

- **17.12.1** To the extent the terms and conditions of this Agreement conflict with the terms of the Collaboration Agreement or the supply agreements, quality agreements, pharmacovigilance agreements, and data protection agreements referenced herein, the terms and conditions of this Agreement shall prevail with respect to the Product; *provided*, that (a) the terms and conditions of such pharmacovigilance agreements shall prevail solely with respect to Product safety matters in accordance with Section 8.2, (b) the terms and conditions of such quality agreements shall prevail with respect to Product quality matters, and (c) the terms and conditions of such data protection agreements shall prevail with respect to personal data.
- **17.12.2** Notwithstanding anything to the contrary, the Collaboration Agreement may not be terminated with respect to the Product for so long as this Agreement continues to survive.
- 17.13 <u>Independent Contractors.</u> Notwithstanding anything contained herein to the contrary, SGI and Genmab each agree and acknowledge that they shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, agency, or any type of fiduciary relationship. Neither SGI nor Genmab shall have the authority to make any statements, representations or commitments of any kind, or take any action, which shall be binding on the other Party, without the prior Party Written Consent of the other Party to do so.

#### **17.14** <u>Affiliates</u>.

- **17.14.1** Except as provided in this Section 17.14, either Party may perform any or all of its obligations under this Agreement through one or more Affiliates (but only for so long as such Person is and remains an Affiliate of such Party); provided, that such Party shall remain fully liable for the obligations under this Agreement and any acts or omissions of such Affiliates. Each Party shall cause its respective Affiliates to comply fully with the provisions of this Agreement to the extent such provisions specifically relate to, or are intended to specifically relate to, such Affiliates, as though such Affiliates were expressly named as joint obligors hereunder. In addition, notwithstanding any limitations in the Collaboration Agreement, each Party shall have the right to extend the rights, licenses, immunities and obligations granted in this Agreement and the Collaboration Agreement to one or more of its Affiliates (but only for so long as such Person is and remains an Affiliate of such Party) and any such extension to Affiliates under the Collaboration Agreement prior to the Effective Date is hereby deemed approved. All applicable terms and provisions of this Agreement and the Collaboration Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the extending Party.
- **17.14.2** To the extent required by Applicable Law, the Parties shall cause their relevant local Affiliates in any country in the Territory to enter into local agreements to implement the arrangements provided for in this Agreement. Such implementing agreements shall be in forms mutually agreed by the Parties and shall be, in all material respects, consistent with the terms and conditions of this Agreement, including by having termination provisions that are not inconsistent with <u>ARTICLE 14</u>.
- 17.15 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver

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relating to a particular matter for a particular period of time.

- 17.16 <u>Fees and Expenses</u>. Except as otherwise specified in this Agreement, each Party shall bear its own costs and expenses (including investment banking and legal fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby.
- 17.17 <u>Counterparts</u>. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by delivery of electronically scanned copies of original signatures delivered by electronic mail, and such signatures shall be deemed to bind each Party as if they were original signatures; *provided*, that each Party shall also provide the other Party a hard copy of the executed Agreement.

{Signature Pages Follow}

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#### **CONFIDENTIAL**

IN WITNESS WHEREOF, the Parties have caused this Joint Commercialization Agreement to be executed by their duly authorized representatives as of the Effective Date.

Jan van de Winkel		_
	Jan van de Winkel President & CEO	

**GENMAB A/S** 

## **CONFIDENTIAL**

IN WITNESS WHEREOF, the Parties have caused this Joint Commercialization Agreement to be executed by their duly authorized representatives as of the Effective Date.

SEAGEN INC.	
By: Clay B. Siegall, Ph.D. President and Chief Executive Officer	
[*] = Certain information contained in this document, marked material and is the type of information that we treat as private	

## **SCHEDULE 1.6 APPROVED SUBCONTRACTORS**

## For SGI:

Approved Subcontractor	Services/Functions:	
[*]	[*]	

## For Genmab:

Approved Subcontractor	Clinical Trial(s)	Services/Functions
[*]	[*]	[*]

#### **SCHEDULE 1.44 EUROPE**

## The United Kingdom:

- · England
- · Scotland
- · Wales
- · Northern Ireland

#### <u>EU</u>:

- · Austria
- · Belgium
- · Bulgaria
- Croatia
- · Republic of Cyprus
- · Czech Republic
- · Denmark
- · Estonia
- · Finland
- · France
- · Germany
- · Greece
- · Hungary
- · Ireland
- · Italy
- · Latvia
- · Lithuania
- · Luxembourg
- · Malta
- · Netherlands
- · Poland
- · Portugal
- · Romania
- · Slovakia
- · Slovenia
- · Spain
- · Sweden

## EFTA:

- · Iceland
- · Liechtenstein
- · Norway
- · Switzerland

## **SCHEDULE 3.1 GENMAB US ACTIVITIES**

	US Commercialization and Medical Affairs Activities
1. Commercialization	· Genmab fields fifty percent (50%) of the Parties' aggregate Sales
	Representatives for the Product in the United States, as determined on an
	FTE basis.
2. Medical Affairs	· Genmab fields fifty percent (50%) of the Parties' aggregate MSLs for the
	Product in the United States, as determined on an FTE basis.
3. First and Second Line	. [*].
Management	

#### SCHEDULE 5.3.4 CERTAIN U.S. FEDERAL INCOME TAX MATTERS

- Section 1.1. <u>Tax Partnership</u>. The activities of the Partners pursuant to the Agreement in respect of the Development and Commercialization of the Product are deemed to be conducted by the Tax Partnership; provided that the activities of SGI and Genmab with respect to the Royalty Territory are deemed to be activities conducted by SGI and Genmab outside of the Tax Partnership. The partners of the Tax Partnership are SGI and Genmab (the "<u>Partners</u>"). The Tax Partnership, and the rights and obligations set forth in this <u>Schedule 5.3.4</u>, shall be effective beginning on the Tax Partnership Formation Date and shall remain in existence until the Agreement is terminated.
- Section 1.2. <u>Definitions</u>. Capitalized terms used, but not defined, herein will have the meanings ascribed to them in the Agreement. For purposes of this <u>Schedule 5.3.4</u>:
- (a) "<u>Adjusted Capital Account</u>" has the meaning set forth in Section 1.4(d) of this <u>Schedule</u> <u>5.3.4</u>.
- (b) "<u>Book</u>" means the method of accounting prescribed for compliance with the capital account maintenance rules set forth in Section 1.704-1(b)(2)(iv) of the Treasury Regulations, as distinguished from any accounting method which a Partner may adopt for other purposes such as financial reporting.
- (c) "<u>Budget Act</u>" means Section 1101 of the Bipartisan Budget Act of 2015 and any Sections of the Tax Code or Treasury Regulations promulgated thereunder and with respect thereto, each as amended from time to time, and other guidance that may be promulgated in the future relating thereto.
- (d) "<u>Capital Account</u>" has the meaning set forth in Section 1.4(a) of this <u>Schedule 5.3.4</u>.
- (e) "<u>Capital Contribution</u>" means, for each Partner, such Partner's cash or property deemed contributed to the Tax Partnership.
- (f) "<u>Designated Individual</u>" has the meaning set forth in Section 1.9(c) of this <u>Schedule</u> 5.3.4.
  - (g) "Fiscal Year" means the calendar year.
- (h) "Gross Asset Value" means, with respect to any asset of the Tax Partnership, the asset's adjusted basis for federal income tax purposes, adjusted to reflect any adjustments required or permitted by Sections 1.704-1(b)(2)(iv)(d) through (g), (m) and (s) of the Treasury Regulations, as mutually agreed upon by the Partners; provided, that in the case of any asset (other than cash) deemed contributed to the Tax Partnership, the initial Gross Asset Value of such property shall be equal to the fair market value of such asset as of the date of contribution, as mutually agreed upon by the Partners.
- [\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

- (i) "<u>Net Income</u>" and "<u>Net Losses</u>" shall mean the Book income, gain, loss, deductions and credits of the Tax Partnership in the aggregate or separately stated, as appropriate, as of the close of each Taxable Year on the Tax Partnership's tax return filed for federal income tax purposes (or other allocation period).
  - (j) "Partners" has the meaning set forth in Section 1.1 of this Schedule 5.3.4.
- (k) "<u>Partnership Representative</u>" has the meaning set forth in Section 1.9(c) of this Schedule 5.3.4.
  - (l) "Tax Code" means the U.S. Internal Revenue Code of 1986, as amended.
- (m) "<u>Taxable Year</u>" means the Tax Partnership's Fiscal Year or such other year as may be required by Section 706 of the Tax Code.
- (n) "<u>Treasury Regulations</u>" means regulations (whether in final, proposed or temporary form) promulgated by the U.S. Department of the Treasury under the Tax Code, as amended.

Section 1.3. <u>Capital Contributions</u>.

[\*]

Section 1.4. Capital Accounts.

[\*]

Section 1.5. <u>Distributions</u>.

[\*]

Section 1.6. <u>Allocation of Net Income or Net Losses</u>. [\*]. Section 1.7. <u>Regulatory Allocations</u>.

[\*]

Section 1.8. Tax Allocations.

[\*]

Section 1.9. <u>Tax Reports, Tax Elections, Partnership Representative and Designated Individual</u>.

[\*]

Section 1.10. <u>Tax Information Sharing</u>. [\*].

Section 1.11. <u>Tax Position</u>. [\*].

Section 1.12. <u>Termination of Tax Partnership</u>.[\*].

Section 1.13. <u>Costs and Expenses</u>. [\*].

## SCHEDULE 6.3 MANUFACTURING

## **Existing CMO Agreements:**

NAME OF THIRD PARTY CMO	ROLE	RELATIONSHIP PARTY	AGREEMENT
[*]	[*]	[*]	[*]

## **Pending CMO Agreements:**

NAME OF THIRD PARTY CMO	ROLE	RELATIONSHIP PARTY	STATUS
[*]	[*]	[*]	[*]

<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

[\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

# Collaboration and License Agreement

between

Genmab A/S

as Genmab

and

AbbVie Biotechnology Ltd.

as Licensee

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SCHED	ULE 4 – EXISTING THIRD PARTY AGREEMENTS	
	ULE 5 – SUMMARY OF PAYMENT AND OTHER OBLIGATIONS UNDER EXISTING THIRD AGREEMENTS	
SCHED	ULE 6 – GENMAB PATENT RIGHTS	
SCHED	ULE 7 – PERMITTED SUBCONTRACTORS	

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

SCHEDULE 8 - GLOBAL DEVELOPMENT PLAN

SCHEDULE 9 - INTERIM DEVELOPMENT WORK PLANS

SCHEDULE 10 - FINANCIAL SCHEDULE

SCHEDULE 11 – PRESS RELEASE

SCHEDULE 12 - PROJECTED DEVELOPMENT BUDGETS AND TIMELINES

SCHEDULE 13 - DEVELOPMENT MANUFACTURING AND SUPPLY PLANS

SCHEDULE 14 - GMAPS

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

#### **BETWEEN:**

- (1) **GENMAB A/S**, ("<u>Genmab</u>"), CVR no. 2102 3884, a Danish corporation having its principal office at Kalvebod Brygge 43, 1560 Copenhagen V, Denmark; and
- (2) **ABBVIE BIOTECHNOLOGY LTD.**, ("<u>Licensee</u>"), a corporation organized under the laws of Bermuda, having a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda,

(each a "Party" and together, the "Parties").

#### **BACKGROUND:**

- (A) Genmab and its Affiliates have developed certain Licensed Compounds and Licensed Products in respect of which it Controls certain Intellectual Property Rights, and have broad expertise in the field of research, development and manufacturing of human antibodies.
- (B) Licensee is an international biopharmaceutical company with considerable knowledge and experience in developing, manufacturing, promoting and marketing biopharmaceutical products throughout the world.
- (C) Genmab and Licensee believe that a collaboration between the Parties would be desirable to expand and accelerate the development, and maximize the future commercial potential, of the Licensed Products.
- (D) The Parties intend to jointly research, develop, manufacture and commercialize the Licensed Products worldwide as part of a global collaboration as described in this Agreement, including jointly setting the strategies, monitoring execution of the plans, making decisions on investments to be made and deployment of resources, and prioritizing activities with the aim of maximizing the value of the Licensed Products for the benefit of patients and stakeholders. The Parties desire to create integrated teams to achieve shared objectives for the successful development, launch, manufacture and commercialization of the Licensed Products in the Field worldwide, subject to the terms and conditions set out herein.
- (E) As further described in this Agreement, Genmab is further developing its capabilities related to the development and commercialization of biopharmaceutical products, and the Parties intend this collaboration and Agreement to accommodate that development. As such, the Parties intend to collaborate on the terms set forth in this Agreement to assist Genmab to learn from Licensee's infrastructure, procedures and best practices in connection with the Licensed Products as Genmab develops its infrastructure, procedures, practices and capabilities.
- (F) In addition to the Licensed Compounds and Licensed Products as at the Effective Date which are set out in this Agreement, the Parties wish to enter into a separate Research and Collaboration Agreement for the development of additional compounds. If any such additional compounds are selected by Licensee to be taken forwards for Development and Commercialization under this Agreement pursuant to the mechanism set out in the Research and Collaboration Agreement (and summarized in Schedule 2), then such additional compound shall become a Licensed Compound hereunder and treated as described in Schedule 2.

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(G) All capitalized terms used in these recitals shall have the meanings given in clause 1 below.

**NOW, THEREFORE,** for and in consideration of the mutual covenants contained herein, Genmab and Licensee agree as follows:

#### 1. <u>Definitions and interpretation</u>

1.1 In this Agreement and in the Schedules to this Agreement the following words and phrases shall have the following meanings:

"Acquirer" shall mean for the purposes of:

- (A) part (A) of the definition of "Change of Control", the entity acquiring all or substantially all of a Party's assets;
- (B) part (B) of that definition, the entity which possesses a majority of the voting power and power of election as contemplated by that part; or
- (C) part (C) of that definition, the entity which does possess a majority of the voting power and power of election as contemplated by that part.

"Action" shall mean any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

"[\*] Option Target" shall have the meaning set out in Schedule 2.

"Additional Costs" shall have the meaning set out in clause 6.3.1.

"Affiliate" shall mean with respect to any Party, any Person controlling, controlled by or under common control with such Party. For purposes of this definition, "control" shall mean: (A) in the case of a Person that is a corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such Person; and (B) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management of or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

"Agreement" shall mean this Collaboration and License Agreement.

"Alliance Managers" shall have the meaning set out in clause 3.9.

"Audited Site" shall have the meaning set out in clause 6.6.5.

"Bankruptcy Code" shall have the meaning set out in clause 16.5.2.

"Biosimilar" shall mean: (A) in respect of a Licensed Product sold in the United States, a biological product approved under the Public Health Service Act 351(k) that is highly similar to such Licensed Product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the Licensed Product in terms of the safety, purity and potency; (B) in respect of a Licensed Product sold in the EU, a biological product

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approved under Article 10(4) of Directive 2001/83/EC and Section 4, Part II, Annex I to such Directive based on the demonstration of the similar nature of such biological medicinal product and Licensed Product; and (C) in respect of a Licensed Product sold outside the United States and the EU, a biological product approved under a similar regulatory pathway as in the United States and in the EU, if such pathway exists.

"<u>BLA</u>" shall mean a Biologics License Application or equivalent submission filed with the FDA in connection with seeking Regulatory Approval for commercial marketing or sale of the Licensed Products, or an equivalent application filed with any equivalent Regulatory Authority in any jurisdiction or region in the Territory other than the United States.

"Breaching Party" shall have the meaning set out in clause 16.4.

"Business Day" shall mean a day on which banking institutions in (A) Chicago, Illinois, U.S. (B) New Jersey, U.S., and (C) Copenhagen, Denmark are open for business.

"Calendar Quarter" shall mean the three (3) calendar month periods commencing on 01 January, 01 April, 01 July and 01 October. References to "quarterly" shall be construed accordingly.

"Calendar Year" shall mean the period commencing on 01 January and ending on 31 December.

"Cap" shall have the meaning set out in clause 8.4.

"CAPA" shall have the meaning set out in clause 6.6.5.

"Change of Control" shall mean: (A) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of a Party's assets; (B) a merger or consolidation in which a Party is not the surviving corporation or in which, if a Party is the surviving corporation, the shareholders of such Party immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, own a majority of the stock or other securities of the entity or the ultimate parent entity of such entity that possess a majority of the voting power of all of the Party's outstanding stock and other securities and the power to elect a majority of the members of the Party's board of directors; or (C) a transaction or series of related transactions (which may include without limitation a tender offer for a Party's stock or the issuance, sale or exchange of stock of a Party) in which the shareholders of such Party immediately prior to the initiation of such transaction do not, but immediately after consummation of such transaction or any of such related transactions, own stock or other securities of the Party's outstanding stock and other securities and the power to elect a majority of the members of the Party's board of directors, provided that a Change of Control excludes any transaction (or series of related transactions) in which the pre-transaction stockholders of the applicable Party own more than 50% of the outstanding capital stock or equity interests of the surviving or acquiring entity or its parent.

"Claim" shall have the meaning set out in clause 15.19.3.

"Clinical Data" shall mean all information with respect to any Licensed Compound or Licensed Product which is made, collected, or otherwise generated under or in connection with Clinical Studies, including any data (including raw data), reports, and results with respect thereto.

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"Clinical Studies" shall mean collectively any human studies designed to measure the safety or efficacy of the Licensed Products, including any Phase I Clinical Studies, Phase II Clinical Studies and Phase III Clinical Studies, post marketing commitment studies, Phase IV Clinical Studies and any other study in which human subjects are dosed with a drug, whether approved or investigational, in each case of the Licensed Products within the Field.

"Clinical Trial Laws" shall mean Laws relating to human Clinical Studies, including 21 C.F.R. Parts 50, 54, 56, 312, and 812 and equivalent laws in other jurisdictions, and then-current Good Clinical Practice, each as in effect and as amended from time to time.

"CMC Development" shall mean the following Development activities: analytical test method development and stability testing, Manufacturing process development and improvement, Manufacturing process validation, Manufacturing process scale-up, formulation development, delivery system development, quality assurance and quality control development, and other related activities.

"Collaboration Technology." shall mean any Intellectual Property Rights conceived and reduced to practice, discovered, developed or otherwise made by or on behalf of a Party, either alone or jointly with the other Party or others, during the Term of this Agreement in connection with the performance of this Agreement (including in connection with the Development, Manufacture and Commercialization of the Licensed Products, such as complementary or companion diagnostic products), including all [\*] that is conceived and reduced to practice, discovered, developed or otherwise made by or on behalf of a Party in connection with the performance of any [\*], but excluding any other [\*] and [\*].

"Commercial Milestone" shall have the meaning set out in clause 11.2.3.

"Commercial Manufacturing and Supply Plans" shall mean those plans prepared in accordance with clause 7.2.4 and incorporated into the GCP regarding the Manufacturing activities to be performed by the Parties in respect of the Licensed Products after Regulatory Approval is obtained for the applicable Licensed Product.

"Commercialization" or "Commercialize" shall mean any and all activities relating to obtaining pricing and reimbursement approvals, marketing, promoting, distributing, importing, exporting, selling or offering to sell a product. Commercialization shall not include any activities related to Development or Manufacturing or Clinical Studies.

"Commercialization Costs" shall mean the [\*] and [\*] incurred by [\*] during the Term in Commercializing the Licensed Products in the Field, in each case to the extent incurred in accordance with this Agreement and the Global Commercialization Plans [\*], including [\*]. Any [\*] shall constitute Development Costs; or [\*] shall constitute Commercialization Costs. For the avoidance of doubt, if Licensed Product is [\*], then [\*]. Notwithstanding the foregoing, Commercialization Costs do not include [\*].

"Commercialization Lead" shall have the meaning set out in clause 3.8.

"Commercialization Projection" shall have the meaning set out in clause 7.2.2.

"Commercially Reasonable Efforts" shall mean the level of efforts and resources of a Party required to, as applicable, Develop and Commercialize a biopharmaceutical product consistent with [\*], taking into account [\*].

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"Committees" shall mean the JSC, JDC and JCC collectively, each referred to individually as a "Committee".

"Competing Party" shall have the meaning set out in clause 18.8.3.

"Competing Product" shall mean: (A) if the Licensed Compound in the Licensed Product is [\*], any [\*] (other than the Licensed Product, but including any Biosimilar with respect thereto); (B) if the Licensed Compound in the Licensed Product is [\*] any [\*] or [\*] approaches that target [\*] (other than the Licensed Product, but including any Biosimilar with respect thereto); (C) if the Licensed Compound in the Licensed Product is [\*], any [\*] or [\*] (other than the Licensed Product, but including any Biosimilar with respect thereto); and (D) if the Licensed Compound in the Licensed Product is any other subsequent Option Compound, the applicable definition of Competing Product as set out in the Research and Collaboration Agreement shall apply. For these purposes, in each case, [\*] shall be a Competing Product as set forth above. Competing Products shall furthermore include [\*] (for the avoidance of doubt save to the extent included in a product concept described in (A) or (C) above).

"Competition Law" shall mean any law of any jurisdiction governing the conduct of businesses or individuals in relation to restrictive or other anticompetitive agreements or practices, public procurement, dominant or monopoly market positions and the control of mergers, acquisitions and joint ventures.

"Confidential Information" shall have the meaning set out in clause 14.1.1.

"Control" or "Controlled" shall mean, with respect to intangible property, the legal authority or right of a Party to grant a license or sublicense of any Intellectual Property Rights to the other Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party or misappropriating the proprietary or trade secret information of a Third Party.

"Core Data Sheet" shall mean a document setting forth material information relating to safety, efficacy, indications, dosing, pharmacology and other information concerning the Licensed Product that will serve as a global reference document and basis for local labeling for use in Regulatory Filings or in discussions with Regulatory Authorities in the Territory.

"Cover", "Covering" or "Covered" shall mean, with respect to a Patent Right for the Licensed Products or related technology, that, [\*].

"Data" shall mean any and all research data, results, pharmacology data, medicinal chemistry data, preclinical data, clinical data (including investigator reports (both preliminary and final), statistical analysis, expert opinions and reports, safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by applicable Laws) and the like, in each case arising out of, generated from, or used in the Development, Manufacture or Commercialization of the Licensed Products hereunder.

"Data Protection Agreement" shall have the meaning set out in clause 13.2.

"<u>Data Security and Privacy Laws</u>" shall mean all applicable Laws relating to the privacy, Processing or security of Personal Data.

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"Data Subject" shall mean any individual to whom the Personal Data relates.

"Designated Country" shall have the meaning set out in clause 7.3.2(A).

"[\*]" shall have the meaning set out in clause 7.3.2(A).

"<u>Detail</u>" shall mean an interactive face-to-face visit by a sales Field Based Representative with a medical professional having prescribing authority or who is able to influence prescribing decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of a biopharmaceutical product are discussed in an effort to increase prescribing preferences of a biopharmaceutical product for its approved uses. Detail includes First Position Detail and Second Position Detail (defined below). Activities conducted by medical support staff (such as medical science liaisons) will not constitute Details. E-details, activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing face-to-face sales calls or not specifically trained with respect to a biopharmaceutical product will not constitute Details. "<u>Detailing</u>" means the act of performing Details and to "<u>Detail"</u> means to perform Details. For such purposes:

"<u>First Position Detail</u>" means a Detail in which the applicable biopharmaceutical product is Detailed before any other product and the predominant portion of time is devoted to the Detailing of such biopharmaceutical product.

"Second Position Detail" means a Detail in which the applicable biopharmaceutical product is Detailed in the second position (i.e., no more than one other product is presented to or discussed with the healthcare professional before such product) and the second most predominant portion of time is devoted to the Detailing of such biopharmaceutical product.

"<u>Development</u>" or "<u>Develop</u>" shall mean any and all non-clinical and clinical research and drug development activities relating to obtaining or maintaining Regulatory Approvals of the Licensed Products, including toxicology, pharmacokinetic studies, pharmacology and other discovery efforts, translational research and biomarker activities, CMC Development activities, statistical analysis, Clinical Studies (including pre-Regulatory Approval studies (e.g. Phase I Clinical Studies, Phase II Clinical Studies and Phase III Clinical Studies), post-Regulatory Approval studies (e.g. Phase IV Clinical Studies) and post-Regulatory Approval investigator sponsored Clinical Studies), regulatory affairs activities, and Regulatory Approval and Clinical Study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals), but otherwise excludes Manufacture and Commercialization activities.

"<u>Development Costs</u>" shall mean [\*] and [\*] incurred by the Parties and their Affiliates during the Term in Developing the Licensed Products in the Field, in each case to the extent incurred in accordance with this Agreement and the Global Development Plans (including the Global Development Budgets), including:

- (A) [\*]
- (B) [\*]
- (C) [\*]

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- (D) [\*]
- (F) [\*]
- (G) [\*]
- (H) [\*]
- (I) [\*]

Development Costs shall exclude [\*]

"Development Lead" shall have the meaning set out in clause 3.8.

"<u>Development Manufacturing and Supply Plans</u>" shall mean those plans prepared in accordance with clause 6.2.1(E) and incorporated into the GDP regarding the Manufacturing activities to be performed by the Parties in respect of the clinical supply of Licensed Products.

"Development Milestone" shall have the meaning set out in clause 11.2.1.

"Dispute" shall have the meaning set out in clause 17.1.

"<u>Drug Regulation Laws</u>" shall mean Laws regulating drugs and pharmaceutical products, including the Federal Food, Drug, and Cosmetic Act, 21 USC. § 301 et. seq., the Prescription Drug Marketing Act of 1987, the federal Controlled Substances Act, 21 USC. § 801 et. seq., and policies issued by the FDA and equivalent laws and policies in other jurisdictions in the Territory, each as in effect and as amended from time to time.

"DuoBody Option Target" shall have the meaning set out in Schedule 2.

"<u>DuoBody Platform Technology</u>" shall mean Genmab or its Affiliate's proprietary platform technology described in the Genmab Technology Patent Rights listed in Schedule 6 and related Know-How [\*]. DuoBody Platform Technology, as described above, shall comprise proprietary technology existing as of the Effective Date or at any time during the Term, including any Collaboration Technology which is directed to the DuoBody Platform Technology [\*]. [\*].

"<u>DuoHexaBody Platform Technology</u>" shall mean Genmab or its Affiliate's proprietary platform technology described in the Genmab Technology Patent Rights listed in Schedule 6 and related Know-How [\*]. DuoHexaBody Platform Technology, as described above, shall comprise proprietary technology existing as of the Effective Date or at any time during the Term, including any Collaboration Technology which is directed to the DuoHexaBody Platform Technology [\*].

"EAP Expenses" shall mean the [\*].

"<u>Early Access Program</u>" or "<u>EAP</u>" shall mean any program to provide patients with a Licensed Product prior to Regulatory Approval and prior to First Commercial Sale in any country in the Territory. Early Access Programs include treatment INDs / protocols, named patient programs and compassionate use programs in other countries. For

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clarity, an EAP with respect to any of the Licensed Products may continue to be performed following Regulatory Approval of such Licensed Product and costs may continue to be incurred in accordance with the performance of such EAP after Regulatory Approval.

"Effective Date" shall mean the date written in the first sentence of the preamble to this Agreement.

"EMA" shall mean the European Medicines Agency or any successor agency thereto.

"Enforcing Party" shall have the meaning set out in clause 12.4.2(A).

"EPO" shall have the meaning set out in clause 12.3.1.

"<u>European Union</u>" or "<u>EU</u>" shall mean the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be expanded or reduced from time to time after the Effective Date, and the United Kingdom and Switzerland.

"Excess Amounts" shall have the meaning set out in clause 8.3.

"Executive Officers" shall mean (A) for Genmab, the [\*] of Genmab (or his/her designee having the requisite decision-making authority and expertise within Genmab to make decisions related to the Dispute so referred to such designee) and (B) for Licensee, the [\*] of Licensee (or his/her designee having the requisite decision-making authority and expertise within Licensee to make decisions related to the Dispute so referred to such designee). If the position of any of the [\*] identified in this definition no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable [\*] shall be replaced with another [\*] with responsibilities and seniority comparable to the eliminated [\*].

"Existing Third Party Agreements" shall mean the agreements listed in Schedule 4.

"FDA" shall mean the United States Food and Drug Administration or any successor agency thereto.

"Field" shall mean all diagnostic, prophylactic and therapeutic uses in human beings.

"Field Based Representative" shall have the meaning set out in clause 7.13.1.

"<u>First Commercial Sale</u>" shall mean, with respect to the Licensed Products in a country or region, the first commercial sale of such Licensed Products in such country or region [\*]. Sales for [\*] or similar uses shall not constitute a First Commercial Sale. In addition, sales of the Licensed Products by and between a Party and its Affiliates, or between the Parties (or their respective Affiliates), shall not constitute a First Commercial Sale.

"Force Majeure" shall mean any event or circumstance which is beyond the reasonable control of a Party, which a Party could not reasonably be expected to have taken into account on the Effective Date, and which results in or causes the failure of that Party to perform any or all of its obligations under this Agreement. Force Majeure shall include an act of God, act of terrorism, voluntary or involuntary compliance with any Law or order of any government, war, civil commotion, labor strike or lock-out, epidemic, pandemic, failure or default of public utilities or common carriers or destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. [\*]

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"FTE" shall mean a full-time equivalent person Calendar Year of scientific, technical, regulatory, commercial, financial or professional work (consisting of a total of [\*] hours per Calendar Year) in directly performing Development, Manufacturing or Commercialization activities in respect of the Licensed Products notwithstanding standard time off for vacations, public holidays, sick leave and the like. For the avoidance of doubt, [\*].

"FTE Costs" shall mean the product of: (A) that number of FTEs (proportionately, on a per- FTE basis) used by a Party or its Affiliates in directly performing activities assigned to such Party under and in accordance with the GDP, GMAP and GCP (and all plans incorporated into any of them) (or for purposes of calculating Development Costs, under and in accordance with the GDPs), multiplied by (B) the applicable FTE Rate (as defined below).

"FTE Rate" shall mean a global blended rate [\*] per FTE. The FTE Rate shall be adjusted [\*] by the percentage movement in the consumer price index [\*] in respect of the immediately preceding Calendar Year

"GAAP" shall mean United States generally accepted accounting principles applied on a consistent basis. Unless otherwise defined or stated, financial terms shall be calculated by the accrual method under GAAP.

#### [\*] shall mean:

- (A) [\*], as further described in Schedule 1, and
- (B) [\*] which, in the case of this subclause (B), are (i) discovered or created by Licensee or its Affiliates in connection with the performance of activities hereunder, either alone or jointly with Genmab, or (ii) discovered or created by or on behalf of Genmab or its Affiliates prior to the Effective Date, or in connection with the performance of activities hereunder, either alone or jointly with Licensee.

[\*].

"[\*] Product" shall mean a Licensed Product containing [\*], provided, however, that if a [\*].

"[\*]" shall mean:

- (A) [\*], as further described in Schedule 1, and
- (B) [\*] which, in the case of this subclause (B) are, (i) discovered or created by Licensee or its Affiliates in connection with the performance of activities hereunder, either alone or jointly with Genmab, or (ii) discovered or created by or on behalf of Genmab or its Affiliates prior to the Effective Date, or in connection with the performance of activities hereunder, either alone or jointly with Licensee.

[\*]

"[\*] Product" shall mean a Licensed Product containing [\*], provided, however, that if a [\*]

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"[\*]" shall mean:

- (A) [\*], as further described in Schedule 1 and having, as of the Effective Date, the INN name epcoritamab, and
- (B) [\*] which in the case of this subclause (B), are (i) discovered or created by Licensee or its Affiliates in connection with the performance of activities hereunder, either alone or jointly with Genmab, or (ii) discovered or created by or on behalf of Genmab or its Affiliates prior to the Effective Date, or in connection with the performance of activities hereunder, either alone or jointly with Licensee.

[\*]

"[\*] Product" shall mean a Licensed Product containing [\*].

"Genmab Agreement Wind-Down Period" shall have the meaning set out in clause 16.8.2(D).

"Genmab Collaboration Technology" shall have the meaning set out in clause 12.2.2.

"Genmab Collaboration Technology Patent Rights" shall have the meaning set out in clause 12.1(E).

"Genmab Indemnified Parties" shall have the meaning set out in clause 15.19.2.

"Genmab Intellectual Property." shall mean: (i) Genmab Know-How; (ii) Genmab Patent Rights; (iii) any other Genmab Collaboration Technology; (iv) Genmab's right in and to any Joint Collaboration Technology; and (v) any other [\*] or [\*] Controlled by Genmab or its Affiliates which, in the case of subclause (v), is necessary to Develop, Manufacture or Commercialize the Licensed Products. For the avoidance of doubt, Genmab Intellectual Property shall not include any Patent Rights licensed to or acquired by Genmab pursuant to clause 12.9 if the Parties have not agreed to such license.

"Genmab Invalidity Claim" shall have the meaning set out in clause 12.5.1.

"Genmab Know-How" shall mean any Know-How that is necessary for or directly related to the Development, Manufacture and Commercialization of the Licensed Compounds or Licensed Products in the Field as contemplated by this Agreement that either: (A) is Controlled by Genmab or any of its Affiliates on the Effective Date; or (B) comes within Genmab's or its Affiliate's Control any time during the Term (including Know-How subsisting in the Genmab Collaboration Technology, Know-How subsisting in [\*] which is Controlled by Genmab or its Affiliates).

"Genmab's Knowledge" shall mean the good faith understanding of the facts and information known by the [\*] of Genmab, or any personnel holding positions equivalent to such job titles (but only to the extent such positions exist at Genmab), each after [\*].

"Genmab Licensed Patent Rights" shall have the meaning set out in clause 12.1(C).

"Genmab Opt-In Right" shall have the meaning set out in clause 7.3.2(A).

"[\*]" shall have the meaning set out in clause 7.3.2(B).

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"Genmab Patent Rights" shall mean Patent Rights that: (A) Cover the [\*] or Genmab Know-How (including for the avoidance of doubt Patent Rights claiming [\*]; and (B) are (1) Controlled by Genmab or its Affiliates as of the Effective Date or (2) become Controlled by Genmab or its Affiliates at any time during the Term (including: (i) those Patent Rights in respect of Genmab Collaboration Technology, (ii) Patent Rights in respect of [\*] which is Controlled by Genmab which is necessary to Develop, Manufacture or Commercialize the Licensed Products, and (iii) those Patent Rights licensed to or acquired by Genmab pursuant to clause 12.9 with the agreement of the Parties). A list of Genmab Patent Rights existing as of the Effective Date which Cover the [\*] is attached hereto as Schedule 6 which shall be updated by Genmab from time to time.

"Genmab Product Patent Rights" shall have the meaning set out in clause 12.1(A).

"Genmab Representatives" shall have the meaning set out in clause 7.3.1(B).

"Genmab Reserved Patent Rights" shall have the meaning set out in clause 12.1.

"Genmab Right to Proceed or Right to Combine Patent Rights" shall have the meaning set out in clause 12.1(C)

"Genmab Technology Patent Rights" shall have the meaning set out in clause 12.1(B).

"Global Brand Plans" shall have the meaning set out in clause 7.5.1.

"Global Commercialization Budgets" shall mean the consolidated budgets for conducting Commercialization activities in respect of each of the Licensed Products in accordance with the applicable Global Commercialization Plan during [\*] thereafter, as well as a high-level estimate of such budgeted amounts for the [\*], as developed by the JCC and approved by the JSC, which budgets shall be updated and amended concurrently with and as part of the Global Commercialization Plans in accordance with the procedures set out in this Agreement.

"Global Commercialization Plans" or "GCPs" shall mean the plans for the Commercialization strategy for each of the Licensed Products in the Field worldwide during [\*], as reviewed by the JCC and amended and updated from time to time in accordance with the procedures set out in this Agreement. For the avoidance of doubt, there shall be one (1) GCP per Licensed Product. Each Global Commercialization Plan shall, among other items, include: [\*]; (iv) the Territory Commercialization Plans for the applicable Licensed Product; (v) the Territory Commercialization Budgets for the applicable Licensed Product; (vi) the Commercial Manufacturing and Supply Plan for the applicable Licensed Product; and (vii) Global Pricing Strategy for each Licensed Product.

"Global Development Budgets" shall mean the consolidated budgets for conducting Development of each of the Licensed Products pursuant to the Global Development Plans during [\*], as developed by the JDC and approved by the JSC, which budgets shall be updated and amended concurrently with and as part of the Global Development Plans in accordance with the procedures set out in this Agreement.

"Global Development Plans" or "GDPs" shall mean the plans for the Parties' Development of each of the Licensed Products in the Field worldwide during [\*], as reviewed by the JDC and amended and updated from time to time in accordance with the procedures set out in this Agreement. For the avoidance of doubt, there shall be

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one (1) GDP per Licensed Product. Each GDP shall, among other items, include: [\*] and (iii) the Development Manufacturing and Supply Plan for the applicable Licensed Product. The initial GDP for the [\*] Product is attached hereto as Schedule 8.

"Global Medical Affairs Budgets" shall mean the consolidated budgets for conducting Medical Affairs activities in respect of each of the Licensed Products in accordance with the applicable Global Medical Affairs Plan during [\*], as developed by the JMAS and reviewed by the JDC (with respect to any portion of the GMAP that pertains to Medical Affairs activities prior to Regulatory Approval of a Licensed Product) and JSC (with respect to any portion of the GMAP that pertains to Medical Affairs activities after Regulatory Approval of a Licensed Product), and in both cases approved by the JSC, which budgets shall be updated and amended concurrently with and as part of the Global Medical Affairs Plans in accordance with the procedures set out in this Agreement.

"Global Medical Affairs Plans" or "GMAPs" shall mean the plans for the Parties' worldwide Medical Affairs strategy in respect of the Licensed Products in the Field to be implemented before and after Regulatory Approval of the Licensed Product has been obtained, which shall comply with the GDP and GCP (and their corresponding budgets), as amended and updated from time to time by the JMAS and reviewed by the JDC (with respect to any portion of the GMAP that pertains to Medical Affairs activities prior to Regulatory Approval of a Licensed Product) and JSC (with respect to any portion of the GMAP that pertains to Medical Affairs activities after Regulatory Approval of a Licensed Product), as applicable, and in both cases approved by the JSC, in accordance with the procedures set out in this Agreement. The initial GMAPs for the [\*] are attached hereto as Schedule 14.

"Global Pricing Strategy" shall have the meaning set out in clause 7.2.5.

"Global Publication Strategies" shall have the meaning set out in clause 14.3.1.

"Global Regulatory Plans" shall have the meaning set out in Schedule 3 paragraph 6.1.

"Good Clinical Practice" shall mean the current standards for clinical trials for pharmaceuticals, as set out in the ICH guidelines and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by the European Union and Governmental Authorities in countries in which the Licensed Products are intended to be sold to the extent such standards are not less stringent than United States Good Clinical Practice.

"Good Laboratory Practice" shall mean the current standards for laboratory activities for pharmaceuticals, as set out in the FDA's Good Laboratory Practice regulations or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which the Licensed Products are intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.

"Good Manufacturing Practice" shall mean the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. § 210 and 211, European Directive 2003/94/EC, Eudralex 4, Annex 16, and applicable United States,

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European Union and ICH Guidance and regulatory requirements for a pharmaceutical product, as amended from time to time.

"Governance Dispute" shall have the meaning set out in clause 3.6.

"Government Health Care Programs" shall mean the Medicare program (Title XVIII of the Social Security Act), the Medicaid program (Title XIX of the Social Security Act), TRICARE, the Federal Employee Health Benefits Program, and other foreign, federal, state and local governmental health care plans and programs.

"Governmental Authority" shall mean: (A) any federal, state or local government, or political subdivision thereof; or (B) any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power; or (C) any court or tribunal (or any department, bureau or division thereof); or (D) any governmental arbitrator or arbitral body.

"Health Care Laws" shall mean Laws relating to Government Health Care Programs, Private Health Care Plans, privacy and confidentiality of patient health information and human biological materials, including, in the United States, federal and state Laws pertaining to the federal Medicare and Medicaid programs (including the Medicaid rebate program); federal Laws pertaining to the Federal Employees Health Benefit Program, the TRICARE program and other Government Health Care Programs; federal and state Laws applicable to health care fraud and abuse, kickbacks, physician self-referral and false claims (including 42 USC. § 1320a-7a, 42 USC. § 1320a-7b, 42 USC. § 1395nn and the federal Civil False Claims Act, 31 USC. § 3729 et. seq.); the Health Insurance Portability and Accountability Act of 1996; and 45 C.F.R. Part 46, as well as other similar Laws in other jurisdictions in the Territory, each as in effect and as amended from time to time.

"<u>HexaBody Platform Technology</u>" shall mean Genmab or its Affiliate's proprietary technology described in the Genmab Technology Patent Rights listed in Schedule 6 and related Know-How [\*]. HexaBody Platform Technology, as described above, shall comprise proprietary technology existing as of the Effective Date or at any time during the Term, including any Collaboration Technology which is directed to the HexaBody Platform Technology [\*]. For clarity, HexaBody Platform Technology excludes [\*]

"ICDR" shall have the meaning set out in clause 17.2.1.

"<u>ICH</u>" shall mean the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

"IND" shall mean an investigational new drug application filed with the FDA or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application or a clinical trial exemption, or any other equivalent or related regulatory submission, license or authorization.

"Indemnified Party" shall have the meaning set out in clause 15.19.3.

"Indemnifying Party" shall have the meaning set out in clause 15.19.3.

"Indication" shall mean, with respect to a Licensed Product:

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- (A) [\*] or, to the extent applicable, any comparable labeling section outside the United States; or
- (B) the approved use of such Licensed Product for [\*].

Notwithstanding the foregoing, the following shall not result in a new or separate Indication: [\*].

"Infringement Claim" shall have the meaning set out in clause 12.6(A).

"<u>Initiation</u>" or "<u>Initiate</u>" shall mean, with respect to a Clinical Study, the first dosing of the first human subject in such Clinical Study.

"Institutional Review Board" shall mean an independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects, as defined by the ICH's efficacy guidelines on Good Clinical Practice, as may be amended from time to time.

"Intellectual Property Rights" shall mean rights to inventions, Patent Rights, Know-How, copyright and related rights, moral rights, rights in confidential information and trade secrets, trademarks, rights in get up and trade dress, goodwill and the right to sue for passing off or unfair competition, database rights, rights in designs and all other intellectual property rights in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

"JCC" shall have the meaning set out in clause 3.3.1.

"JDC" shall have the meaning set out in clause 3.2.1.

"[\*]" shall [\*].

"Joint Chemistry, Manufacturing & Controls Subteam" or "JCMCS" shall have the meaning set out in clause 3.4.2.

"Joint Finance Subteam" or "JFS" shall have the meaning set out in clause 3.4.3.

"[\*]" shall [\*].

"Joint Medical Affairs Subteam" or "JMAS" shall have the meaning set out in clause 3.4.5.

"Joint Planning Team" or "JPT" shall have the meaning set out in clause 3.4.8.

"Joint Regulatory Subteam" or "JRS" shall have the meaning set out in clause 3.4.4.

"Joint Translational Research/Biomarker Subteam" shall have the meaning set out in clause 3.4.6.

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"JSC" shall have the meaning set out in clause 3.1.1.

"Know-How" shall mean any formulas, methods, technical information, processes, procedures, techniques, compositions, plans, data (excluding Data), inventions, discoveries, trade secrets, in each case that is not generally known, and whether patentable or not.

"Launched Licensed Products" shall have the meaning set out in clause 16.8.2(D).

"Law" shall mean any applicable laws, statutes, standard, ordinance, code, rule, regulation, resolution or promulgation having the binding effect of law of any applicable Governmental Authority of: (A) any government of any country; (B) any state, province, county, city or other political subdivision thereof; (C) any supranational body, or (D) any license, franchise, permit or similar right granted under any of the foregoing. For the avoidance of doubt, the definition of "Law" shall include Health Care Laws, Drug Regulation Laws and Clinical Trial Laws.

"Lead" shall have the meaning set out in clause 3.8.

"<u>Licensed Compounds</u>" shall mean: (A) [\*]; and (B) any Option Compound in respect of which Licensee has exercised its Option to License.

"<u>Licensed Products</u>" shall mean any pharmaceutical preparation containing any of the Licensed Compounds as an active ingredient in any dosage form, formulation, presentation, line extension or package configuration.

"<u>Licensed Products Liability Costs</u>" shall mean [\*] resulting from the Development, Manufacture or Commercialization of any of the Licensed Products pursuant to this Agreement.

"<u>Licensed Product Trademarks</u>" shall mean any trademarks as may be proposed by either Party and approved by the JCC for use in connection with the Commercialization of any of the Licensed Products in the Field anywhere in the world, or accompanying logos, trade dress or indicia of origin.

"Licensee Agreement Wind-Down Period" shall have the meaning set out in clause 16.8.3(D).

"Licensee Collaboration Technology" shall have the meaning set out in clause 12.2.3.

"Licensee Indemnified Parties" shall have the meaning set out in clause 15.19.1.

"Licensee Intellectual Property" shall mean: (i) Licensee Know-How; (ii) Licensee Patent Rights; (iii) any other Licensee Collaboration Technology; (iv) Licensee's right in and to any Joint Collaboration Technology; and (v) any other [\*] Controlled by Licensee or its Affiliates which, in the case of subclause (v), is necessary to Develop, Manufacture or Commercialize the Licensed Products. As of the Effective Date, [\*]. For the avoidance of doubt, Licensee Intellectual Property shall not include any Patent Rights [\*].

"Licensee Invalidity Claim" shall have the meaning set out in clause 12.5.1.

"<u>Licensee Know-How</u>" shall mean any Know-How that is necessary for or directly related to the Development, Manufacture or Commercialization of the Licensed

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Compounds or Licensed Products as contemplated by this Agreement that either: (A) is Controlled by Licensee or its Affiliates on the Effective Date (if any); or (B) comes within Licensee's or its Affiliate's Control at any time during the Term (including Know-How subsisting in Licensee Collaboration Technology or [\*] which is Controlled by Licensee or its Affiliates).

"Licensee Patent Rights" shall mean Patent Rights that: (A) Cover any Licensed Products or Licensee Know-How ([\*]); and (B) are (1) Controlled by Licensee or its Affiliates as of the Effective Date (none exists) or (2) become Controlled by Licensee or its Affiliates at any time during the Term (including (i) those Patent Rights in respect of Licensee Collaboration Technology or (ii) [\*] which is Controlled by Licensee which is necessary to Develop, Manufacture or Commercialize the Licensed Products and (iii) those Patent Rights licensed to or acquired by Licensee pursuant to clause 12.9 with the agreement of the Parties).

"Losses" shall have the meaning set out in clause 15.19.1.

"Major European Market" shall mean each of [\*]

"<u>Managed Care Organizations</u>" shall mean pharmacies, pharmacy benefit managers, managed health care organizations, accountable care organizations, group purchasing organizations, large employers, long-term care organizations, formularies, Governmental Authorities and government health care programs (e.g., the U.S. Department of Veterans Affairs and Medicare in any form), and similar programs or organizations.

"<u>Manufacturing</u>" or "<u>Manufacture</u>" shall mean any and all activities directed to producing, manufacturing, processing, filling, finishing, packaging, labelling, quality control, quality assurance testing and release, shipping and storage of a product, but excludes Development and Commercialization.

"Manufacturing Costs" shall mean [\*] and [\*] incurred in connection with: [\*], in each case in respect of any of the Licensed Products. If Licensed Products are Manufactured by a Party or its Affiliates (rather than a Third Party Subcontractor), [\*].

"Medical Affairs" shall mean the following activities of medical affairs personnel (including medical science liaisons) related to the Licensed Products: (A) providing input and assistance with consultancy meetings, recommending investigators and providing support for Clinical Studies and providing input in the design of trials, and delivering non-promotional scientific exchanges and conducting non-promotional activities such as presenting new Clinical Studies and other scientific information; (B) providing grants to support continuing medical education or symposia for educational needs related to the Licensed Products, including with respect to its therapeutic use; (C) development, publication, presentation and dissemination of publications relating to the Licensed Products; (D) responding to medical inquiries and providing medical information services in response to inquiries communicated via Field Based Representatives or received by letter, phone call or email, in each case, from healthcare professionals; (E) managing EAPs; (F) providing appropriate support for investigator-initiated Clinical Studies; and (G) arranging meetings with or giving presentations to (in-person or otherwise) physicians, administrators, or other professionals identified in the GMAPs or Territory Medical Affairs Plans that are conducted in a hospital setting or with Managed Care Organizations with respect to clinical value and outcomes; and (H) conducting clinical value and outcomes activities with any hospital, health system, Managed Care Organization or any other Person.

"Medical Affairs Costs" shall mean [\*] and [\*] incurred by the Parties and their Affiliates during the Term in connection with Medical Affairs activities performed in any country in the Territory, to the extent incurred in accordance with this Agreement and the GMAPs.

"Milestone(s)" shall have the meaning set out in clause 11.2.3.

"Multi-Compound Product" shall mean a Licensed Product containing [\*]

"Net Sales" shall mean, with respect to the Licensed Products, [\*]

- (A) [\*]
- (B) [\*]
- (C) [\*]
- (D) [\*]
- (E) [\*]
- (F) [\*]
- (G) [\*]
- (H) [\*]
- (I) [\*]

[\*].

"Net Sales Reconciliation Procedures" shall have the meaning set out in clause 11.3.1.

"New License Agreement" shall have the meaning set out in clause 4.3.5.

"New Third Party Patent Rights" shall mean, [\*]

"Non-Breaching Party" shall have the meaning set out in clause 16.4.

"Non-[\*] Product" shall mean any Licensed Product other than the [\*] Product.

"Non-Proceeding Party" shall have the meaning set out in clause 6.3.1.

"Non-Sponsor" shall have the meaning set out in clause 6.8.1.

"Non-Substantive Amendment" shall mean any change to the GDP [\*]

"On-Going Clinical Study" shall have the meaning set out in clause 16.8.2(C).

"Option Compound" shall mean each therapeutic candidate discovered or developed by Genmab under an Option Development Plan for an Option Program under the Research and Collaboration Agreement.

"Option Development Plan" shall have the meaning set out in Schedule 2.

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- "Option Program" shall mean the research and development program performed by the Parties in respect of an Option Target pursuant to the Research and Development Agreement.
- "Option Target(s)" shall mean the Targets nominated by a Party as required under the Research and Development Agreement.
- "Option to License" shall have the meaning set out in Schedule 2.
- "Other Income" shall mean any payment or income (other than Net Sales, royalties received by Genmab under clause 11.4, Tax credits or other governmental subsidies) received by a Party or its Affiliate from a Third Party in connection with the grant of a sublicense or other right or activity with respect to the Licensed Products (including, any upfront, milestone, royalty or other payment received from a sublicensee). Notwithstanding the foregoing, [\*]
- "Other Licensed Compound" shall have the meaning set out in clause 11.2.4.
- "Out-of-Pocket Costs" shall mean amounts paid to Third Parties in respect of goods, services or other materials in connection with the Licensed Products and the performance of activities under the GDP, GMAP or GCP (including all plans incorporated into any of them) (or such amounts paid to Third Parties for other activities included in the Shared Costs). For clarity, Out-of-Pocket Costs do not include [\*]
- "Patent Costs" shall mean: [\*]
- "<u>Patent Rights</u>" shall mean any and all of the following: (A) patent applications (including provisional patent applications) and patents (including the inventor's certificates); (B) any substitution, extension (including supplementary protection certificate), registration, confirmation, reissue, continuation, divisional, continuation-in-part, reexamination, renewal, extensions or additions, or the like thereof or thereto; and (C) any foreign counterparts of any of the foregoing.
- "Patient Samples" shall have the meaning set out in clause 6.7.
- "Payee" shall have the meaning set out in clause 11.6.2.
- "Payor" shall have the meaning set out in clause 11.6.2.
- "PDE" or "Primary Detail Equivalent" shall mean a primary Detail equivalent where (i) a First Position Detail has one value of PDE and (ii) a Second Position Detail has another value of PDE; such PDE values to be determined by the JCC and approved by the JSC at a mutually agreed time. The PDE values may depend on various factors, including whether the sales Field Based Representatives carry one single product or more than one product.
- "<u>PDE Costs</u>" shall mean, for sales Field Based Representatives, [\*]. As used herein, references to a "<u>sales Field Based Representative</u>" mean a Field Based Representative utilized to perform Details for Licensed Products.
- "<u>Person</u>" shall mean any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

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"<u>Personal Data</u>" shall mean (A) all information identifying, or in combination with other information, identifiable to an individual, including pseudonymized (key-coded) Clinical Data containing such information; and (B) any other information that is governed, regulated or protected by one or more Data Security and Privacy Laws.

"Pharmacovigilance Agreement" shall have the meaning set out in clause 7.10.1.

"Phase I Clinical Study." shall mean a human clinical study of the Licensed Products that is intended to initially evaluate the safety, metabolism and pharmacokinetics of the Licensed Products or that would otherwise satisfy the requirements of 21 C.F.R. 312.21(a) or an equivalent clinical study in a country in the Territory other than the United States.

"Phase II Clinical Study" shall mean a human clinical study of a Licensed Products for which the primary endpoints include a determination of safety, dose ranges or an indication of efficacy in patients being studied as described in 21 C.F.R. §312.21(b), or an equivalent clinical study in a country in the Territory other than the United States, and that is prospectively designed to generate sufficient data (if successful) to commence a Pivotal Trial.

"Phase III Clinical Study" shall mean a human clinical study of a Licensed Products (regardless of whether actually designated as "Phase III") that is prospectively designed, along with other Phase III Clinical Studies, to demonstrate statistically whether Licensed Products are safe and effective for use in humans in the indication being investigated as described in 21 C.F.R. §312.21(c), or an equivalent clinical study in a country in the Territory other than the United States.

"Phase IV Clinical Study" shall mean a post-marketing study to delineate additional information about a pharmaceutical product's risks, benefits, and optimal use, commenced after receipt of Regulatory Approval in the Indication for which such trial is being conducted, including a trial that would satisfy the requirements of 21 CFR 312.85 or an equivalent clinical study in a country in the Territory other than the United States.

"Pivotal Trial" shall mean any:

- (A) Phase III Clinical Study; or
- (B) other Clinical Study of a pharmaceutical or biologic product conducted on a sufficient number of human subjects in an indicated patient population (i) that is prospectively designed to provide sufficient data (together with any prior data and information concerning such product in such indication) to meet the standards or requirements established by the applicable Regulatory Authority in a particular jurisdiction for demonstrating the safety and efficacy in such indication and filed pursuant to 21 U.S.C. § 356(c)(1)(A) or equivalent Laws in a country in the Territory other than the United States; or (ii) for which the applicable Regulatory Authority has agreed that the design would support an application for Regulatory Approval of such product in such indication in such jurisdiction; or (iii) that becomes a registrational Clinical Study as evidenced by (A) the acceptance of a BLA submission supported by such Clinical Study as a registrational study by the applicable Regulatory Authority (if such acceptance mechanism exists in such country), or (B) the filing of a BLA submission supported by such Clinical Study as a registrational study to the applicable

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Regulatory Authority (if no such formal acceptance mechanism for BLAs exists in such country).

"Potential Target" shall have the meaning set out in clause 2.2.

"Pre-Biosimilar Launch Average" shall have the meaning set out in clause 11.4.5.

"Pre-Tax Profit or Loss" shall mean the total amount of profit or loss incurred by the Parties in connection with Net Sales of the Licensed Products in the Territory, before application of any income Taxes or other direct Taxes, as further described in clause 11.3 and Schedule 10. Where used in the foregoing sentence, "profit or loss" incurred by the Parties with respect to a given Licensed Product shall be calculated using the [\*] of such Licensed Product, regardless of whether such costs are incurred prior to or following the First Commercial Sale of a given Licensed Product.

"<u>Private Health Care Plans</u>" shall mean non-governmental Third Party health care payors and plans, including insurance companies, health maintenance organizations and other managed care organizations, Blue Cross and Blue Shield plans and self-funded employers.

"Prior CDA" shall mean the Confidential Disclosure Agreement between [\*].

"Proceeding Party" shall have the meaning set out in clause 6.3.1.

"<u>Processing</u>" (or its conjugates) shall mean any operation or set of operations that is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alternation, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

"Proprietary Product" shall have the meaning set out in clause 6.4.

"Reconciliation Procedures" shall mean the Net Sales Reconciliation Procedures and Shared Costs Reconciliation Procedures.

"Region" shall mean each of the following: (A) all of the countries in Territory A as a whole; (B) all of the countries in Europe as a whole; and (C) all other countries in the world as a whole that are not described in clauses (A) or (B). For clarity, any country that is both in Europe and in Asia will be considered to be solely in Europe for the purposes of this definition.

"Regulatory Approval" shall mean all approvals, licenses, registrations or authorizations of the applicable Regulatory Authority necessary for the Commercialization of a Licensed Products in the Field or the conduct of Clinical Studies in a country, excluding separate pricing or reimbursement approvals that may be required, and including the expansion or modification of the label for additional Indications or uses.

"Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the Commercialization of a pharmaceutical product in a country, including the FDA in the United States, the Pharmaceuticals and Medical Devices Agency in Japan, and the EMA, Swissmedic and UK Medicines and Healthcare products Regulatory Agency in the EU.

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"Regulatory Filing" shall mean any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to any of the Licensed Products, or their use or potential use in humans, including any documents submitted to any Regulatory Authority and all supporting Data, including INDs and BLAs and all correspondence with any Regulatory Authority with respect to any Licensed Products (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

"Regulatory Milestone" shall have the meaning set out in clause 11.2.2.

"Reimbursed Clinical Study" shall have the meaning set out in clause 6.3.3.

"Research and Collaboration Agreement" shall mean the research and collaboration agreement to be entered into by the Parties promptly following the Effective Date pursuant to clause 2.

"Right to Combine Mechanism" shall mean the mechanism described in clause 6.4.

"[\*]" shall mean any Intellectual Property Rights conceived and reduced to practice, discovered, developed or otherwise made by or on behalf of a Party (either alone or jointly with others) during the Term of this Agreement in connection with activities performed by such Party under the Right to Combine Mechanism. [\*]

"Right to Proceed Mechanism" shall mean the mechanism described in clause 6.3.

"[\*]" shall mean any Intellectual Property Rights conceived and reduced to practice, discovered, developed or otherwise made by or on behalf of a Party (either alone or jointly with others) during the Term of this Agreement in connection with activities performed by such Party under the Right to Proceed Mechanism. [\*]

"Royalty Bearing Product" shall have the meaning set out in clause 11.4.1.

"Royalty Report" shall have the meaning set out in clause 11.4.4.

"Royalty Term" shall mean the period commencing upon First Commercial Sale of the Royalty Bearing Product in any country or territory in Territory B and continuing for so long as such Royalty Bearing Product is being sold in such country or territory by Licensee or its Affiliates.

"Sales Force PDE Rate" shall mean [\*], as adjusted [\*] by the percentage movement in the consumer price index [\*] in respect of the immediately preceding Calendar Year.

"Shared Costs" shall have the meaning set out in clause 8.1.

"Shared Costs Reconciliation Procedures" shall have the meaning set out in clause 8.2.

"Shared Licensed Products Liability Costs" shall have the meaning set out in clause 15.20.1.

"[\*]" shall mean [\*].

"SOPs" shall mean standard operating procedures.

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- "Sponsor" shall have the meaning set out in clause 6.8.1.
- "Subcontract" shall have the meaning set out in clause 5.1.
- "Subcontractor" shall have the meaning set out in clause 5.1.
- "Substantive Amendments" shall mean any change to the GDP, GMAP, GCP (including to any plans incorporated into the GDP, GMAP or GCP), the Global Publication Strategies, or any of their respective budgets which is not a Non-Substantive Amendment, such as [\*]; (v) any other amendment which results in a change in any specific part (set forth as a line item) of the applicable budget of more than [\*]; and (vi) any other item which the JSC expressly identifies as constituting a Substantive Amendment if amended.
- "Subteam" shall have the meaning set out in clause 3.4.1.
- "Supply Agreement" shall have the meaning set out in clause 10.1.2.
- "<u>Target</u>" shall mean a protein, polypeptide, fragments and post-translationally modified versions thereof. To the extent possible such Target shall be identified by its amino acid sequence and coded by a genetic locus, or UniProt-Swiss number or similar unique identifier.
- "<u>Tax</u>" shall mean any present or future taxes, levies, imposts, duties, charges, withholdings, assessments or fees of any nature (including interest, penalties and additions thereto), and "<u>Taxes</u>" shall be construed accordingly.
- "Term" shall have the meaning set out in clause 16.2.
- "Terminated Product" shall have the meaning set out in clause 16.8.1.
- "Terminated Region" shall have the meaning set out in clause 16.8.1.
- "Termination Royalty Term" shall have the meaning set out in clauses 16.8.2(F) or 16.8.3(F), as applicable.
- "Territory" shall mean Territory A and Territory B.
- "Territory A" shall mean the United States and Japan.
- "<u>Territory B</u>" shall mean the entire world and all countries, territories and possessions therein, excluding Territory A.
- "Territory B Major Markets" shall mean: [\*]
- "Territory Medical Affairs Plans" shall mean the plans for the Parties' Medical Affairs activities for the Licensed Products in the Field in specific countries or regions in the Territory, which shall be incorporated into, form part of and comply with the GMAP (and their corresponding budgets), as amended and updated from time to time by the JMAS and reviewed by the JDC (with respect to any portion of the GMAP that pertains to Medical Affairs activities prior to Regulatory Approval of a Licensed Product) or JSC (with respect to any portion of the GMAP that pertains to Medical Affairs activities after Regulatory Approval of a Licensed Product), as applicable, and in each case approved by the JSC, in accordance with the procedures set out in this Agreement.

"<u>Territory Commercialization Budgets</u>" shall mean the budgets for conducting the Commercialization activities in specific countries or regions in the Territory set out in the applicable Territory Commercialization Plans during a given Calendar Year and the successive Calendar Year thereafter, as well as a high-level estimate of such budgeted amounts for the second successive Calendar, which shall form part of, and comply with, the Global Commercialization Budgets.

"Territory Commercialization Plans" shall mean the commercialization plans with respect to Commercialization activities for the Licensed Products in the Field in specific countries or regions in the Territory, in each case [\*] (including the Territory Commercialization Budgets and annual Net Sales forecasts for the relevant countries and regions) which shall be incorporated into, form part of and comply with, the Global Commercialization Plans, as amended from time to time in accordance with the procedures set out in this Agreement.

"Third Party" shall mean any Person other than a Party (including its Affiliates).

"Third Party Licensed Products Liability Action" shall have the meaning set out in clause 15.20.2.

"United States" or "U.S." shall mean the United States of America and its territories and possessions.

"USPTO" shall have the meaning set out in clause 12.3.1.

"<u>Valid Claim</u>" shall mean a claim of any unexpired Patent Right (whether granted or an application) that has not been revoked, cancelled or held unpatentable, unenforceable or invalid by a decision of a court or Governmental Authority of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed, abandoned, cancelled, or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

"WAC" shall have the meaning set out in clause 7.2.5.

- 1.2 Headings and titles to the clauses and Schedules of this Agreement are inserted for convenience only and shall not be deemed a part hereof or affect the construction or interpretation of any provision herein.
- 1.3 Unless the context otherwise requires, all references to a particular clause or Schedule shall be a reference to that clause or Schedule in or to this Agreement.
- 1.4 Unless the contrary intention appears, words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa. Except where the context otherwise requires, wherever used, the word "or" is used in the inclusive sense (and/or).
- 1.5 Any phrase introduced by the terms "<u>including</u>", "<u>include</u>", "<u>in particular</u>" or any similar expression shall be construed as illustrative and shall not limit the generality of the words preceding those terms.
- 1.6 Any reference to a statute, statutory provision or subordinate legislation (legislation) (except where the context otherwise requires): (A) shall be deemed to include any by laws, licenses, statutory instruments, rules, regulations, orders, notices, directions,

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consents or permissions made under that legislation; and (B) shall be construed as referring to any legislation which replaces, re-enacts, amends or consolidates such legislation (with or without modification) at any time.

- 1.7 The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.
- 1.8 Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

#### 2. Research Collaboration Agreement

- 2.1 As soon as reasonably practicable after the Effective Date, the Parties shall commence good faith negotiations and endeavour to agree on the terms of the Research and Collaboration Agreement in respect of the further research and development of the Option Targets which shall be based on, and incorporate, the terms set out in Schedule 2. The Parties shall endeavour to reach agreement on the terms of such Research and Collaboration Agreement as soon as practicable and, in any event, prior to the [\*] following the Effective Date and, if the Parties so agree to such terms, shall enter into such Research and Collaboration Agreement promptly following reaching agreement on such terms, but in no event prior to the Effective Date.
- 2.2 <u>Potential Targets</u>. The Parties anticipate that from time to time prior to the date on which they enter into the Research and Collaboration Agreement, either Party may disclose to the other Party up to [\*] Targets intended as potential [\*] Option Targets and up to [\*] Targets intended as potential [\*] Option Targets that such disclosing Party is interested in nominating as an [\*] Option Target or [\*] Option Target (as applicable) in accordance with the terms set out in Schedule 2. Promptly following the disclosure of any such Target to the other Party, such other Party shall confirm in writing whether such Target is an Unavailable Target as further described in Schedule 2 (each such Target confirmed in writing that is not an Unavailable Target, a "Potential Target"). From the Effective Date until the earlier of: (A) the date on which the Parties enter into the Research and Collaboration Agreement; and (B) [\*] following the Effective Date, neither Party shall grant or propose to grant to any Third Party any rights to any Potential Target of the other Party (or an option to obtain such a grant of rights) that would conflict with the proposed terms of the Research and Collaboration Agreement that are set forth in Schedule 2 (as if the terms set forth in Schedule 2 were in full force and effect and otherwise binding upon the Parties as of the Effective Date). For the avoidance of doubt, if an insufficient number of proposed Targets are confirmed as Potential Targets as required under Schedule 2, then up to a further [\*] Targets intended as potential [\*] Option Targets and up to a further [\*] Targets intended as potential [\*] Option Targets may be proposed by the relevant Party until such sufficient number of Option Targets is achieved; however, in no event will a Party be required to

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confirm the availability of more than [\*] Targets intended as potential [\*] Option Targets and [\*] Targets intended as potential [\*] Option Targets at any one time.

#### 3. Governance

#### 3.1 **Joint Steering Committee**

- 3.1.1 <u>Formation and responsibilities</u>. Within [\*] after the Effective Date, the Parties shall establish one (1) joint steering committee (the "<u>JSC</u>") in accordance with clause 3.5, comprised of senior executives, to provide high-level strategic oversight and decision-making regarding the activities of the Parties under this Agreement with respect to all of the Licensed Products.
- 3.1.2 <u>Specific responsibilities of the JSC</u>. Without prejudice to the generality of clause 3.1.1 (and any other provision of this Agreement which grants any express power, authority or right to the JSC), the JSC shall have full power and authority on behalf of the Parties and with the power to bind the Parties thereby, to perform the activities set out in Schedule 3 Part 1.

## 3.2 **Joint Development Committee**

- 3.2.1 Formation. Within [\*] after the Effective Date, the Parties shall establish one (1) joint development committee (the "JDC") for each Licensed Product or for multiple Licensed Products as deemed appropriate by the JSC in accordance with clause 3.5, unless directed otherwise by the JSC, to oversee the Development of each applicable Licensed Product, which shall report to the JSC. In conducting its activities, including in the allocation of activities to the Parties under the applicable GDP, the JDC shall operate and make its decisions consistent with the GDPs, the terms of this Agreement and the Law. For the avoidance of doubt, references to "JDC" in this Agreement shall be construed as referring to the applicable JDC for the applicable Licensed Product.
- 3.2.2 <u>Specific responsibilities of the JDC</u>. Without prejudice to any other provision of this Agreement which grants any express power, authority or right to the JDC, the JDC shall have authority on behalf of the Parties to perform the activities set out in Schedule 3 Part 2.

#### 3.3 Joint Commercialization Committee

3.3.1 Formation. The Parties shall establish one (1) joint commercialization committee (the "JCC") for each Licensed Product or on a multiple Licensed Product basis as deemed appropriate by the JSC in accordance with clause 3.5, to oversee the Commercialization of each applicable Licensed Product, which shall report to the JSC. In conducting its activities, including the allocation of activities to the Parties under the Global Commercialization Plans, the JCC shall operate and make its decisions consistent with the GCPs, the terms of this Agreement and the Law. In addition to its members, the JCC may also consult an equal number of designated representatives from both Parties to advise it on its compliance with relevant Laws and policies. The JCC responsible for the [\*] Product shall be established within [\*] after the Effective Date. The JCCs for the [\*] shall be [\*]. For the avoidance of doubt, references to "JCC" in this Agreement shall be construed as referring to the applicable JCC for the applicable Licensed Product.

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3.3.2 <u>Responsibilities of the JCC</u>. Without prejudice to any other provision of this Agreement which grants any express power, authority or right to the JCC, the JCC shall have authority on behalf of the Parties to perform the activities set out in Schedule 3 Part 3.

#### 3.4 Subteams

- 3.4.1 The JDC or JCC may, as they deem necessary or as directed by the JSC, establish various subteams on a per Licensed Product or per multiple Licensed Product basis in accordance with clause 3.5, to oversee particular projects or activities under this Agreement (each, a "Subteam"), including those Subteams described below in this clause 3.4 and others such as a clinical strategy Subteam, commercial Subteam or market access Subteam. Each Subteam shall be constituted and shall operate as the Committees determine. For the avoidance of doubt, the members of each Subteam may be members of more than one Subteam in respect of different Licensed Products. In conducting their activities, the Subteams shall operate and make their decisions consistent with the terms of this Agreement and the Law. The JDC or JCC may, as they deem necessary or as directed by the JSC, dissolve any Subteam which is no longer necessary or useful. For the avoidance of doubt, references to any specific Subteam in this Agreement shall be construed as referring to such applicable Subteam for the applicable Licensed Product.
- 3.4.2 <u>Joint Chemistry, Manufacturing & Controls Subteam</u>. Within [\*] after the Effective Date, the Parties shall establish a joint CMC Development Subteam on a per Licensed Product or per multiple Licensed Product basis as determined by the JSC, JDC or JCC (the "<u>Joint Chemistry, Manufacturing & Controls Subteam</u>" or "<u>JCMCS</u>") in accordance with clause 3.5, which shall report to the JDC with respect to issues within the decision-making authority of the JDC and to the JCC with respect to issues within the decision-making authority of the JCC. For the avoidance of doubt, references to "Joint Chemistry, Manufacturing & Controls Subteam" or "JCMCS" in this Agreement shall be construed as referring to the applicable Joint Chemistry, Manufacturing & Controls Subteam for the applicable Licensed Product. The JCMCS shall have responsibility for the activities set out in Schedule 3 Part 4.
- 3.4.3 <u>Joint Finance Subteam.</u> Within [\*] after the Effective Date, the Parties shall establish a joint finance Subteam on a per Licensed Product or per multiple Licensed Product basis (the "<u>Joint Finance Subteam</u>" or "<u>JFS</u>") as determined by the JSC, JDC or JCC, in accordance with clause 3.5, which shall report to the JDC with respect to the Development of the Licensed Products, to the JCC with respect to the Commercialization of the Licensed Products and to the JSC with respect to the preparation and approval of Pre-Tax Profit or Loss statements in accordance with the Net Sales Reconciliation Procedures, clause 11.3 and Schedule 10. The JFS shall operate in coordination with the other Committees and Subteams. The JFS shall have responsibility for the activities set out in Schedule 3 Part 5. For the avoidance of doubt, references to the "Joint Finance Subteam" or "JFS" in this Agreement shall be construed as referring to the applicable Joint Finance Subteam for the applicable Licensed Product or multiple Licensed Products.
- 3.4.4 <u>Joint Regulatory Subteam</u>. Within [\*] Business Days after the Effective Date, the Parties shall establish a joint clinical regulatory Subteam on a per Licensed Product or per multiple Licensed Product basis (the "<u>Joint Regulatory Subteam</u>" or "<u>JRS</u>") as determined by the JDC in accordance with clause 3.5, which shall report to the JDC. The JRS shall have responsibility for the activities set out in Schedule 3 Part 6. For

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the avoidance of doubt, references to the "Joint Regulatory Subteam" or "JRS" in this Agreement shall be construed as referring to the applicable Joint Regulatory Subteam for the applicable Licensed Product or multiple Licensed Products.

- 3.4.5 <u>Joint Medical Affairs Subteam.</u> Within [\*] after the Effective Date, the Parties shall establish a joint Medical Affairs Subteam for the [\*] Product. For the Non-[\*] Products, Joint Medical Affairs Subteam(s) shall be established in due course when the Parties are directed to do so by the JSC (each such Subteam, the "<u>Joint Medical Affairs Subteam</u>" or "<u>JMAS</u>") in accordance with clause 3.5, which shall report to the JDC (with respect to any Medical Affairs activities occurring prior to Regulatory Approval of the applicable Licensed Product) and JSC (with respect to any Medical Affairs activities occurring after Regulatory Approval of the applicable Licensed Product). A JMAS may be established on a per Licensed Product or per multiple Licensed Product basis. The JMAS shall have responsibility for the activities set out in Schedule 3 Part 7. For the avoidance of doubt, references to "Joint Medical Affairs Subteam" or "JMAS" in this Agreement shall be construed as referring to the applicable Joint Medical Affairs Subteam for the applicable Licensed Product or multiple Licensed Products.
- 3.4.6 <u>Joint Translational Research/Biomarker Subteam</u>. Within [\*] after the Effective Date, the Parties shall establish a joint translational research/biomarker Subteam on a per Licensed Product or per multiple Licensed Product basis (the "<u>Joint Translational Research/Biomarker Subteam</u>" or "<u>JTRBS</u>") as determined by the JDC in accordance with clause 3.5, which shall report to the JDC. The JTRBS shall have responsibility for the activities accorded to it in the GDP and interim workplans. For the avoidance of doubt, references to "Joint Translational Research/Biomarker Subteam" or "JTRBS" in this Agreement shall be construed as referring to the applicable Joint Translational Research/Biomarker Subteam for the applicable Licensed Product or multiple Licensed Products.
- 3.4.7 [\*].
- 3.4.8 Joint Planning Team. Within [\*] after the Effective Date, the Parties will establish a joint planning team on a per Licensed Product or per multiple Licensed Product basis (each, a "Joint Planning Team" or "JPT"). Each Party's JPT representatives shall include key member(s) of each Subteam specifically listed in this clause 3.4 as well as any other functions deemed relevant for the advancement of such Licensed Product(s). Examples of team representatives may include discovery, precision medicine, preclinical safety, legal, intellectual property, statistics, clinical operations, DMPK, process sciences, manufacturing, market research, product development, commercial, marketing or any other function deemed applicable to the stage of Development or Commercialization for the applicable Licensed Product(s). Other function team members may participate when deemed appropriate by the applicable JPT. Such cross-functional team, led by a program team leader and project manager of each Party (which may be a Development Lead or a Commercial Lead), will be responsible for overseeing the Subteams and other relevant functions including ensuring alignment and synergy amongst the Subteams, streamlining interactions amongst the JDC, JCC and JSC, and ensuring the respective Subteams meet in accordance with clause 3.7. The JPT shall coordinate the flow of information between Subteams in order to ensure preparedness for decision-making at the appropriate governance level. Each JPT shall conduct detailed discussions and bring up matters for further discussions in the relevant Subteams or matters for review or approval in the relevant Committees, but shall have no decisionmaking authority. Either Party

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may replace any or all of its representatives at any time upon written notice (by any written means, including email, and mailed correspondence). Any member of the JPT may designate a substitute to attend and perform the functions of that member at any meeting of the JPT.

## 3.5 Membership

The Committees, Subteams and JPT shall be composed of representatives appointed by each Party, who shall have adequate and appropriate expertise and authority within the relevant functions.

The JSC shall be comprised of [\*] representatives of each Party (or each Party's Affiliates).

The JDC and JCC shall each be comprised of [\*] representatives of each Party. The JSC may determine in due course if more representatives are needed.

The Committees may from time to time change the size of the various Subteams or JPT(s) which report to them. Each Party may replace Committee, Subteam or JPT representatives at any time upon written notice to the other Party. Each Committee and Subteam shall be [\*] one (1) designated representative from [\*]. The [\*] of each Committee and Subteam shall not have any greater authority than any other representative on the Committee or Subteam.

The [\*] shall be responsible for: (i) calling meetings; (ii) preparing and circulating an agenda and any relevant pre-read materials in advance of each meeting, provided that the co-chairpersons shall include any agenda items proposed by either Party on such agenda; (iii) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set out in this Agreement; and (iv) preparing and issuing minutes of each meeting based on contemporaneous notes reflecting the substance of such meeting shared and mutually agreed between the co-chairpersons immediately following or as soon as practicable following such meeting. Notwithstanding the foregoing, such minutes shall be circulated to the other members of the Committee or Subteam no later than [\*] following the relevant meeting for review, comment and approval of each Party. If no comments are received by the co-chairpersons or their delegates within [\*] of receipt of the minutes by a Party's members, unless otherwise agreed, they shall be deemed to be approved by such Party. If the Parties are unable to reach agreement on the minutes within [\*] of the applicable meeting, the sections of the minutes which have been agreed between the Parties by that date shall be deemed approved and, in addition, each Party shall record in the same document its own version of those sections of the minutes on which the Parties were not able to agree. For the avoidance of doubt, each Party may designate the same individual as a representative on more than one Committee or Subteam, and each Party may designate employees of its Affiliates as its representatives (including [\*]) on any of the Committees or Subteams.

## 3.6 **Decision-making**

The Committees and Subteams shall each operate by consensus. With respect to decisions of the Committees and Subteams, the representatives of each Party shall have collectively one (1) vote on behalf of such Party.

If the representatives of any Subteam disagree on any matter that is within its authority under this Agreement for which consensus has been sought but not obtained, the

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matter shall be referred to the Committee to which such Subteam reports, for discussion and resolution.

If the representatives of the JDC or JCC disagree on any matter that is within its authority under this Agreement for which consensus has been sought but not obtained, the matter shall be referred to the JSC for resolution. [\*]. If the representatives of the JSC disagree, either with respect to any matter referred to it by the JDC, JCC or any Subteam directly reporting to it, or with respect to a matter initially arising within the JSC, then such matter shall be considered a "Governance Dispute" and may be referred to resolution in accordance with clauses 17.1 and 17.2.

#### 3.7 Meetings

Each Committee shall hold meetings at such times as each Committee decides (unless otherwise directed by the JSC), but in no event shall such meetings be held less frequently than once every [\*] during the Term for so long as each such Committee exists. Each Subteam shall hold meetings at such times as each Subteam decides, or as the Committee to which it reports directs. Each Party shall bear its own costs in respect of its hosting of, or attendance at, any Committee or Subteam meetings, save that [\*].

Each Committee, the JPT and each Subteam meeting shall be in person or by audio, web conferencing or video conference as the Parties may mutually agree, provided that each Committee meets in person at least once per [\*] during the Term for so long as such Committee exists (save to the extent prevented from doing so as a result of government recommended or imposed travel restrictions). The JPTs and each Subteam has the option but not the requirement to meet in person once per [\*] during the Term for so long as such JPT or Subteam exists. With respect to in-person meetings of the Committees and Subteams, the representatives shall meet alternately at a location designated by Genmab and Licensee respectively. Other representatives of the Parties and their Affiliates involved in the Development, Manufacture or Commercialization of the Licensed Products may attend such meetings of the Committees or Subteams as non-voting observers as deemed necessary at the request of a Party, with prior notification to the other Party. No Third Party representative is permitted to attend a meeting on behalf of a Party without the prior written consent of the other Party. All such observers shall be subject to confidentiality obligations at least as onerous as those in clause 14.

Each Committee, the JPTs and each Subteam may upon agreement meet on an ad hoc basis between regularly scheduled meetings in order to address and resolve time-sensitive issues within their decision-making authority that may arise from time to time. No action taken at such meetings shall be effective unless a representative of each Party is present. Neither Party shall unreasonably withhold attendance of at least one (1) representative of such Party at any meeting of a Committee or Subteam for which reasonable advance notice was provided.

## 3.8 Development and Commercialization Leads

Each Party shall designate one (1) person to lead on the Development of each Licensed Product on its behalf on a single or multiple Licensed Product basis (each, a "<u>Development Lead</u>"), and one (1) person to lead on the Commercialization of each Licensed Product on its behalf on a single or multiple Licensed Product basis (each, a "<u>Commercialization Lead</u>" and collectively the "<u>Leads</u>"). The Development Lead for each Licensed Product shall act as one (1) of the representatives for that Party on the

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applicable JDC. The Commercialization Lead for each Licensed Product shall act as one (1) of the representatives for that Party on the applicable JCC. A Party may elect to have the same person act as its Development Lead or Commercialization Lead for more than one Licensed Product.

Such Leads will be responsible for facilitating collaboration between the Committees and Subteams, with respect to Development and Commercialization, respectively. Such Leads shall have adequate and appropriate expertise and authority within the relevant functions. The Leads shall attend all [\*], and work closely with the Alliance Managers of each Party and the JPT(s) to facilitate and enable a successful collaboration. [\*] after the Effective Date, each Party shall notify the other Party in writing of the name of its Leads with respect to [\*] and thereafter a Party may replace its Leads at any time upon written notice of the same to the other Party. [\*] after the Effective Date, each Party shall notify the other Party in writing of the name of its Development Leads with respect to [\*] and [\*], and shall notify the other Party of the Commercialization Lead for [\*] and [\*] when the JCCs are established in due course at the direction of the JSC. Thereafter a Party may replace its Leads at any time upon written notice of the same to the other Party.

#### 3.9 Alliance Managers

Each Party shall designate one (1) alliance manager for all of the activities contemplated under this Agreement for each of the Licensed Products (the "Alliance Managers"), save that a Party may elect to have one person act as its Alliance Manager for more than one Licensed Product. Such Alliance Managers will be responsible for the day-to-day worldwide coordination of the collaboration contemplated by this Agreement in respect of their allocated Licensed Product and act as a point of contact between the Parties to facilitate communication between the Parties or perform any other functions as deemed appropriate by the JSC. Such Alliance Managers shall have experience and knowledge appropriate for managers with such alliance management responsibilities, including without limitation a general understanding of product development and Commercialization. An Alliance Manager may bring any matter to the attention of any Committee if such Alliance Manager reasonably believes that such matter warrants such attention. The Alliance Managers shall attend all Committee, JPT and Subteam meetings to the extent possible for their respective Licensed Product and work closely with the Development Leads and Commercialization Leads for such Licensed Product to facilitate and enable a successful collaboration. In addition, Alliance Managers shall attend any joint meetings of the Parties regarding the Agreement that are held independent of the Committees or Subteams. Within five (5) Business Days after the Effective Date, each Party shall notify the other Party in writing of the name of its Alliance Managers and thereafter a Party may replace its Alliance Managers at any time upon written notice of the same to the other Party.

# 3.10 Limitations on the authority of Committees and Subteams

- (A) No rights, powers, or discretion shall be delegated to or vested in a Committee or Subteam unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties agree otherwise in writing.
- (B) No Committee or Subteam shall have the authority to amend or waive the terms and provisions of this Agreement, other than by way of amending or

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updating the GDP, GMAP or GCP (or any other plans incorporated into any of them) in accordance with its powers under this Agreement.

#### Licenses

#### 4.1 Genmab grant

- 4.1.1 Subject to the terms and conditions of this Agreement, Genmab hereby grants Licensee a co-exclusive license or sublicense (as applicable) under the Genmab Intellectual Property to: (i) Develop and have Developed the Licensed Compounds and Licensed Products; (ii) make, have made and otherwise Manufacture the Licensed Compounds and Licensed Products; and (iii) use, sell, offer to sell, have sold, import and otherwise Commercialize the Licensed Compounds and Licensed Products, in each case solely for purposes of performing activities as set forth in, and subject to the terms of, this Agreement during the Term in the Field in the Territory. For the avoidance of doubt, the term "co-exclusive" shall mean that only Genmab and Licensee shall have the right to use the Genmab Intellectual Property to the exclusion of all others (save for permitted sublicensees under clause 4.3). No licenses are granted to Licensee with respect to [\*] of each of the Licensed Products except for use of [\*] in connection with the Manufacture of the Licensed Products and as required for the Development of the Licensed Products in accordance with the GDPs.
- 4.1.2 Existing Third Party Agreements. The sublicenses granted in clause 4.1.1 with respect to Intellectual Property Rights licensed to Genmab under the Existing Third Party Agreements are subject to limitations, conditions and obligations set forth in the Existing Third Party Agreements. [\*]. Licensee acknowledges and agrees that it has been provided with copies of such material Existing Third Party Agreements prior to the Effective Date, [\*]. The Parties acknowledge and agree that the Existing Third Party Agreement between Genmab and [\*] is fundamental to the continued Development, Manufacture and Commercialization of the [\*] Product. As between the Parties, Genmab shall be solely liable to perform any obligations under the Existing Third Party Agreements. [\*].

#### 4.2 Licensee grant

Subject to the terms and conditions of this Agreement, Licensee hereby grants, and shall cause its Affiliates to grant, to Genmab, a co-exclusive license under the Licensee Intellectual Property to: (i) Develop and have Developed the Licensed Compounds and Licensed Products; (ii) make, have made and otherwise Manufacture the Licensed Compounds and Licensed Products; and (iii) use, sell, offer to sell, have sold, import and otherwise Commercialize the Licensed Compounds and Licensed Products, in each case solely for purposes of performing activities as set forth in, and subject to the terms of, this Agreement during the term in the Field in the Territory. For the avoidance of doubt, the term "co-exclusive" shall mean that only Genmab and Licensee shall have the right to use the Licensee Intellectual Property to the exclusion of all others (save for permitted sublicensees under clause 4.3).

# 4.3 Sublicensing

4.3.1 <u>Sublicensing Generally.</u> Save to the extent provided otherwise in clauses 4.3.2 and 4.3.3, neither Party may sublicense the rights granted to it under clauses 4.1 or 4.2.

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- 4.3.2 <u>Permitted Sublicensing</u>. Notwithstanding any provision in this Agreement to the contrary, each Party shall have the right to grant a sublicense of the rights granted to it under clauses 4.1 or 4.2 to: (i) an Affiliate of such Party to perform a Party's obligations as described in clause 4.3.6; or (ii) a Third Party to perform under a Subcontract entered into with such Third Party pursuant to clause 5. [\*]. For the avoidance of doubt, the sublicensing Party under clauses 4.3.2 or 4.3.3 shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for the acts and omissions of its sublicensees as if they were its own acts and omissions under this Agreement.
- 4.3.3 <u>Approved Sublicensing.</u> Notwithstanding clause 4.3.1, Licensee may sublicense the rights granted to it under clause 4.1 to a Third Party in order to Develop, Manufacture or Commercialize any of the Licensed Products in:
  - (A) [\*] subject to [\*] obtaining the JSC's prior consent to such sublicensing. [\*].
  - (B) [\*] subject to [\*] obtaining the JSC's prior consent to such sublicensing. [\*].

For the avoidance of doubt, subject to clause 4.3.2, [\*].

- 4.3.4 On a Licensed Product-by-Licensed Product and country-by-country basis, with respect to a given Licensed Product [\*], if Licensee desires to grant to a Third Party a sublicense of the rights granted to it under clause 4.1 to Commercialize Licensed Products [\*].
- 4.3.5 [\*]. Upon termination of this Agreement by Genmab pursuant to clauses 16.4, 16.5 or 16.6, upon the request of any sublicensee of Licensee described in clause 4.3.3 above, Genmab will enter into [\*] (each a "New License Agreement"), provided that such sublicensee: [\*]. Under such New License Agreement, Genmab will not be bound by any [\*].
- 4.3.6 <u>Performance by Affiliates</u>. The Parties agree that any Affiliate of either Party may perform any of that Party's obligations under this Agreement for or on behalf of that Party provided that that Party shall be fully responsible and liable for the actions of such Affiliates in the performance of such obligations and shall ensure that such Affiliates comply with the terms of this Agreement. Nothing in this clause 4.3 shall relieve either Party of any of its obligations under any provision of this Agreement to the extent that such obligation is not satisfied by any purported performance thereof by such Affiliate of that Party.

#### 4.4 Covenants

- 4.4.1 <u>Genmab covenants.</u> Until the expiration or earlier termination of this Agreement with respect to all Licensed Products containing a given Licensed Compound, Genmab covenants to Licensee that Genmab shall not, and shall cause its Affiliates not to, research, develop, Manufacture or Commercialize, for its own account or on behalf of or in collaboration with any Third Parties, any Competing Product with respect to such Licensed Compound for use in the Field. For the avoidance of doubt, pursuant to the definition of Competing Product, Genmab shall have the right to use the [\*] for any purposes other than in [\*]
- 4.4.2 <u>Licensee covenants</u>. Until the expiration or earlier termination of this Agreement with respect to all Licensed Products containing a given Licensed Compound, Licensee covenants to Genmab that Licensee shall not, and shall cause its Affiliates not to,

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research, develop, Manufacture or Commercialize, for its own account or on behalf of or in collaboration with any Third Parties, any Competing Product with respect to such Licensed Compound for use in the Field.

- 4.4.3 <u>Mutual Covenants</u>. Each Party acknowledges and agrees that nothing in this Agreement will be construed as a representation, warranty, covenant or inference that the other Party or its Affiliates will not itself develop, Manufacture or market or enter into business relationships with one or more Third Parties to [\*].
- 4.4.4 <u>Disclaimer</u>. For the avoidance of doubt: (i) any material use by [\*].

## 4.5 No other rights

4.5.1 No rights, other than those expressly set out in this Agreement are granted to either Party hereunder, and no additional rights shall be deemed granted to either Party by implication, estoppel or otherwise, with respect to any Intellectual Property Rights. All rights not expressly granted by either Party or its Affiliates to the other hereunder are reserved.

# 5. **Sub-contracting**

5.1 Required Subcontract Terms. Subject to clauses 5.2 and 10.1.3, each Party may subcontract the performance of any of its obligations under this Agreement to one or more Third Parties (each such Third Party, a "Subcontractor") pursuant to a written agreement (a "Subcontract") which shall: (i) be consistent with the terms and conditions of this Agreement, (ii) contain confidentiality provisions no less restrictive than those set forth in this Agreement, (iii) contain a provision obligating such Subcontractor to assign to such Party all inventions or other intellectual Property Rights developed or invented by such Subcontractor in the course of performing such subcontracted work (other than inventions or other Intellectual Property Rights directed to such Subcontractor's proprietary platform in general), in each case, as necessary to give effect to clause 12.2; (iv) contain a certification that such Subcontractor has not been debarred, and is not subject to debarment, pursuant to Section 306 of the United States Federal Food, Drug and Cosmetics Act, and is not the subject of a conviction described in such section or any similar Laws elsewhere in the Territory. Furthermore, to the extent applicable to the subcontracted work under such Subcontract, each Party shall use reasonable efforts to include in any Subcontract entered into after the Effective Date [\*]. The JDC and JCC shall oversee the performance of Subcontractors, and to the extent permitted under the relevant Subcontract each Party shall have the right from time to time. but not more than [\*], to [\*]. Notwithstanding the foregoing, the subcontracting Party shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for the acts and omissions of its Subcontractors as if they were its own acts and omissions under this Agreement. In addition, each Party shall notify the other Party in writing if it enters into any Subcontract in accordance with this clause 5.

# 5.2 [\*].

(A) [\*]. Notwithstanding clause 5.1 and subject to clause 5.2(C): (i) neither Party may Subcontract any of its obligations under this Agreement relating to [\*]; and (ii) neither Party may Subcontract its [\*] obligations [\*] to a Third Party, in each case ((i) and (ii)), [\*].

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- (B) [\*]. If the [\*] is unable to agree whether to permit [\*] described in clause 5.2(A)(i):
  - (a) to the extent such Subcontracting relates to a [\*], then the matter shall be [\*];
  - (b) to the extent such Subcontracting relates to any country in [\*], then such matter shall be referred to the [\*] for resolution and, if they are unable to reach agreement, then the [\*]; and
  - (c) to the extent such Subcontracting relates to [\*], then the matter shall be [\*].

[\*].

- (C) <u>Exceptions</u>. Notwithstanding clause 5.2(A), no [\*] shall be required for a Party to Subcontract its obligations under the Agreement if: (i) [\*]; (ii) Licensee desires to Subcontract [\*] responsibilities to a Third Party in any country in [\*]; or (iii) either Party desires to Subcontract [\*] obligations other than for [\*] of the Licensed Product such as [\*] of Licensed Products. The Parties acknowledge and agree that, notwithstanding clause 5.2(A), Genmab is permitted to Subcontract its [\*] obligations for the composition of: [\*]
- 5.3 **Licensee consultation**. If Genmab desires to enter into a Subcontract relating to the performance of any of its obligations under this Agreement in [\*], then it shall reasonably consider whether to request [\*] to perform such obligations on a Subcontract basis on its behalf or whether to appoint a Third Party Subcontractor and [\*].

# 6. **Development**

#### 6.1 General

- 6.1.1 <u>Current development status</u>. Prior to the Effective Date, Genmab has independently initiated Clinical Studies of the Licensed Products in the Field. The Parties have agreed to continue the Development of the Licensed Products in the Field in accordance with the GDPs and the terms of this Agreement.
- 6.2 GDPs; GMAPs; Amendments; Development and Medical Affairs Responsibilities
- 6.2.1 Global Development Plans.
  - (A) The global Development of the Licensed Products shall be conducted in accordance with the GDPs, and the Parties agree to conduct all their (and their Affiliates') Development activities relating to the Licensed Products in accordance with the GDPs (subject to clauses 6.3 and 6.4). The initial GDP for the [\*] Product is attached hereto as Schedule 8.
  - (B) The JDC shall prepare initial GDPs for other Licensed Products at a time mutually agreed by the Parties (and in any event [\*] after the Parties have preliminary clinical proof of concept (as agreed by the JSC) for the applicable Licensed Compound and determined the [\*] of such Licensed Compound for any Phase II Clinical Study); such initial GDPs shall then be submitted to the JSC for final approval. Pending such GDPs, the Parties agree that the Parties

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shall execute the Development activities set out in the interim Development workplans appended at Schedule 9.

- (C) The GDPs shall allocate responsibility to a Party for each Development activity, including regulatory and CMC Development activities set out in the GDPs and in accordance with the terms and conditions of this Agreement. The GDPs shall include [\*] and shall be consistent with the terms of this Agreement. Guidelines for additional data or criteria, if any, to be generated for assessment prior to commencement of any specific Clinical Study, shall be included in the GDPs. The GDPs shall also include: (i) the applicable Global Development Budget; and (ii) the Development Manufacturing and Supply Plan for the applicable Licensed Product in respect of activities before Regulatory Approval of that Licensed Product. Any activities set out in the GDPs shall at all times be designed to be in compliance with the Law and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry, taking into account where applicable each Party's health care compliance policies and applicable SOPs.
- (D) The Global Development Budgets included in the GDPs shall include:
  - (a) budgeted amounts for the Development Costs to be incurred in performing the activities allocated to the Parties under the GDPs during the then-current [\*] thereafter, including budgets for each Clinical Study and each category of other Development activities included in the GDP (such categories shall include Manufacturing and any other categories to be determined by the JDC) for each Indication.
  - (b) if the duration of a Clinical Study included in the GDP is anticipated to be longer than [\*], a non-binding forecast of the Development Costs for the entire duration of that Clinical Study;
  - (c) a budget for each Party setting out the Development Costs for the specific Development activities allocated to such Party under such GDP, broken down by [\*] for the then-current [\*].

As part of the annual update of the GDPs, the JDC shall also prepare, with assistance from the JFS, and the JSC shall review and approve as part of the updated GDPs, the applicable updated Global Development Budget covering the [\*] and a forecast of the annual Global Development Budget until receipt of Regulatory Approval for the Indications reflected in such Global Development Budget and for the entire duration of the applicable Clinical Studies.

(E) The Parties shall jointly develop, with the JCMCS, Development Manufacturing and Supply Plans for each Licensed Product setting out the Manufacturing activities to be performed pre-Regulatory Approval of the Licensed Product. Such Development Manufacturing and Supply Plans shall be incorporated into, and form part of, the GDP. Such Development Manufacturing and Supply Plans shall be reviewed and approved as part of the GDP pursuant to clause 6.2.1(A) and updated annually in accordance with procedures set out in clause 9.1. The terms of such Development Manufacturing and Supply Plans shall at all times be designed to be in compliance with the GDP, all applicable Laws, taking into account where applicable each Party's applicable SOPs. The initial Development

Manufacturing and Supply Plans for the Licensed Products for the rest of the Calendar Year after the Effective Date is attached as Schedule 13.

#### 6.2.2 Global Medical Affairs Plans.

- (A) The global Medical Affairs activities for the Licensed Products shall be conducted in accordance with the GMAPs, and the Parties agree to conduct all their (and their Affiliates') Medical Affairs activities relating to the Licensed Products in accordance with the GMAPs. The initial GMAPs for each of the [\*] Product, [\*] Product and [\*] Product are attached at Schedule 14.
- The Global Medical Affairs Plans shall include: (i) the Parties' strategies for Medical Affairs (B) activities for each Licensed Product in the Field in the Territory (including the relative responsibilities of the Parties with respect thereto); (ii) an overview of plans for the size and structure for the Medical Affairs activities team for the applicable Licensed Product and deployment of personnel conducting Medical Affairs activities for such Licensed Product by geography; (iii) such information as the JMAS believes to be necessary for the successful Medical Affairs support of the applicable Licensed Product, such as overall medical strategies, the medical narrative, global advisory boards, publication plans, outcomes/real world evidence strategies, and global strategies for investigator-initiated Clinical Studies; and (iv) the applicable Global Medical Affairs Budget. The Global Medical Affairs Plan shall also include [\*] for such Medical Affairs activities and for the entire duration of any Medical Affairs activities extending beyond such additional [\*]. Such Global Medical Affairs Plans shall be reviewed by the JDC (with respect to any portion of the GMAP that pertains to Medical Affairs activities prior to Regulatory Approval of a Licensed Product) and JSC (with respect to any portion of the GMAP that pertains to Medical Affairs activities after Regulatory Approval of a Licensed Product), as applicable, and approved by the JSC and updated annually in accordance with the procedures set out in clause 9.3. The terms of such Global Medical Affairs Plans shall at all times be designed to be in compliance with the Global Brand Plans and all applicable Laws and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry, taking into account, where applicable, each Party's applicable SOPs.
- (C) Based on the Global Medical Affairs Plans, the Parties shall jointly develop, with the JMAS, Territory Medical Affairs Plans that set forth in further detail the allocation of the pre-Regulatory Approval activities described in clause 6.2.2(B) for the applicable Licensed Product in the Field in specific countries or regions in the Territory. Such Territory Medical Affairs Plans shall also be incorporated into, and form part of, the GMAP. The Territory Medical Affairs Plans shall be reviewed and approved as part of the GMAP pursuant to clause 6.2.2(B) and updated annually in accordance with procedures set out in clause 9.3. The terms of, and activities set out in, such Territory Medical Affairs Plans shall at all times be designed to be in compliance with the GMAP, all applicable Laws and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry, taking into account where applicable each Party's applicable SOPs.

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- (D) The Global Medical Affairs Budgets included in the GMAPs shall include:
  - (a) budgeted amounts for the Medical Affairs Costs to be incurred in performing the Medical Affairs activities allocated to the Parties under the GMAPs during the [\*] thereafter, including each category of Medical Affairs activities included in the GMAP;
  - (b) a budget for each Party setting out the Medical Affairs Costs for the specific Medical Affairs activities allocated to such Party under such GMAP, broken down by [\*] for the then-current [\*].

As part of the annual update of the GMAPs, the JMAS shall also prepare, with assistance from the JFS, and the JDC or JSC (as applicable) shall review and the JSC shall approve as part of the updated GMAPs, the applicable updated Global Medical Affairs Budget covering the next [\*] and a forecast of the annual Global Medical Affairs Budget.

- 6.2.3 <u>Development principles</u>. The Parties intend that Development of the Licensed Products in the Field will be conducted in accordance with the following principles, and the JDC (or the JSC, or the Executive Officers, as applicable) shall take into account and attempt to implement the following principles in its decision-making:
  - (A) [\*]
  - (B) [\*]
  - (C) [\*]
  - (D) [\*]
- 6.2.4 <u>Allocation of Development activities</u>. The GDPs shall allocate responsibility between the Parties for the conduct of Clinical Studies and the various other Development activities addressed in the GDPs.
  - (A) <u>Clinical Studies for [\*]</u>. As further described in the GDP for [\*]:
    - (a) Genmab shall maintain sponsorship for, and conduct: [\*];
    - (b) Genmab shall maintain sponsorship for, and conduct, [\*];
    - (c) Licensee shall maintain sponsorship for, and conduct, [\*]; and
    - (d) Licensee and Genmab shall assume responsibility for the execution and delivery of all other [\*] that are not described in subclause (A) above with the mutual understanding that [\*] shall be responsible for most of such other [\*], provided that [\*] will be entitled to conduct at least [\*]
  - (B) <u>Clinical Studies for other Licensed Products</u>. Each Party's respective responsibilities for executing and delivering all other Clinical Studies for the Licensed Products shall be set forth in the GDPs, which GDPs shall provide that:
    - (a) Genmab shall have the right to assume responsibility and maintain sponsorship for, and conduct [\*];

- (b) Licensee shall have the right to assume responsibility and maintain sponsorship for, and conduct [\*]; and
- (c) If more than [\*] under the applicable GDP, then [\*] shall have the right to assume responsibility and maintain sponsorship for, and conduct, [\*].
- (C) <u>Conduct of Clinical Studies</u>. All Clinical Studies or other Development of Licensed Products in the Field worldwide shall be subject to the terms of the GDPs and other governance and oversight by both Parties as set out in this clause 6. [\*]. Neither Party (nor its Affiliates) shall conduct any Clinical Study or other Development of the Licensed Products in the Field, except as expressly permitted in this clause 6, the GDPs or pursuant to the Right to Proceed Mechanism or Right to Combine Mechanism.

## 6.3 Right to Proceed Mechanism

- 6.3.1 Right to Proceed. If, with respect to a Licensed Product that is the subject of Development activities under a given GDP: (i) prior to [\*] of such Licensed Product, a Party proposes to include in any GDP a new [\*] or [\*] (but not a [\*]) intended to support a [\*] for any [\*] for such Licensed Product; or (ii) after [\*] of such Licensed Product, a Party proposes to include in any GDP [\*] (including a [\*]) intended to support [\*] for such Licensed Product, and in either case the JSC does not approve the addition of such [\*] in the GDP, then such proposing Party (the "Proceeding Party") shall be allowed to [\*] unless the other Party (the "Non-Proceeding Party") acting in good faith:
  - (A) raises reasonable [\*] regarding the proposed [\*];
  - (B) raises reasonable concerns that such [\*] for those [\*] already included in the GDPs or [\*] of the Licensed Product or any already planned or ongoing [\*] under the Right to Proceed Mechanism or Right to Combine Mechanism;
  - (C) in the case of subclause (a) above only, raises reasonable concerns regarding [\*] for the Licensed Product or any other [\*] included in the GDPs or the [\*] associated with such [\*] or a [\*] that is anticipated to be received based on such [\*]; or
  - (D) raises reasonable concerns that such [\*] may result in the [\*] which relate to the Licensed Products or Licensed Compounds that are generated in the performance of that [\*] that would be [\*] if conceived, discovered, developed or otherwise made by the Proposing Party,

and in each case (A)-(D) the Non-Proceeding Party shall provide the basis for such reasonable concerns in reasonable detail in writing (including referencing any objective evidence which it is aware of in respect of such concerns and provided that such evidence is in its possession or is otherwise available in the public domain). If the JSC does not agree to allow any such [\*] to proceed under the GDP, and the Non-Proceeding Party raises any of the concerns set forth in subclauses (A), (B), ((C) if such proposed [\*] would occur prior to [\*] of the applicable Licensed Product) or (D) above, then the [\*] shall discuss and determine whether or not such new [\*] should be permitted to proceed under the Right to Proceed Mechanism. If the [\*] do not agree within [\*] after the matter has been escalated to the [\*], the Non-Proceeding Party shall have the [\*]. If any such new [\*] proceeds, then [\*]. For the avoidance of doubt, if the Proceeding Party does not wish to proceed unilaterally with any proposed [\*] under

this Right to Proceed Mechanism, it may continue to request the inclusion of such [\*] in the GDP in accordance with the dispute resolution mechanism in clause 17.

#### 6.3.2 If such new [\*]:

- (A) results in, or the data from such new [\*] is used in [\*]; or
- (B) is sufficiently successful that the JDC and JSC decide to subsequently perform a [\*] or [\*] in respect of such new [\*] and include this [\*] or [\*] in the GDP,

then the Non-Proceeding Party shall [\*] equal to [\*] the amount which would otherwise have been [\*] by such Non-Proceeding Party in respect of [\*], if the relevant [\*] had been approved by the JSC, pursuant to clause 8.1; provided that such [\*] that would have been [\*] by the Non-Proceeding Party, shall not, for purposes of determining the [\*] by the Non-Proceeding Party pursuant to this paragraph, be [\*] for such [\*] in the Proceeding Party's initial proposed amendment to the GDP. Such [\*] shall include [\*].

- 6.3.3 The [\*] under clause 6.3.2 shall be [\*] by way of [\*] which the Proceeding Party shall issue an invoice for upon achievement of the matters referred to in clause 6.3.2(A) or (B) with payment due [\*] thereafter. At the same time as issuing the invoice, the Proceeding Party shall provide [\*].
- 6.3.4 Upon receiving such [\*] for a [\*], such [\*] will be included in the applicable Global Commercialization Plans and Global Medical Affairs Plans and Commercialized by both Parties pursuant to the applicable Global Commercialization Plans, and the related Manufacturing Costs, Medical Affairs Costs and Commercialization Costs for the Licensed Product in such [\*] shall [\*].

# 6.4 Right to Combine Mechanism

If, with respect to a Licensed Product that is the subject of Development activities under a given GDP: (a) prior to [\*] of such Licensed Product, a Party proposes to include in any GDP a new [\*] or [\*] (but not a [\*]) involving the [\*]; or (b) after [\*] of such Licensed Product, a Party proposes to include in any GDP (including a [\*]) involving the [\*], and in either case the JSC does not approve the addition of such [\*], the proposing Party shall be allowed to conduct such [\*] unless the other Party acting in good faith: (i) raises reasonable potential [\*] regarding the proposed [\*]; (ii) raises reasonable concerns that such [\*] will [\*] of the Licensed Product for those [\*] already included in the applicable GDP or the [\*] of the Licensed Product or any already planned or ongoing [\*] under the Right to Proceed Mechanism or Right to Combine Mechanism; and (iii) in the case of subclause (a) only, raises reasonable concerns regarding [\*] for the Licensed Product or any other [\*] included in the GDPs or the [\*] associated with such [\*] or a [\*] that is anticipated to be received based on such Clinical Study, and in each case (i) - (iii) such other Party shall provide the basis for such reasonable concerns in reasonable detail in writing (including referencing any objective evidence which it is aware of in respect of such concerns and provided that such evidence is in its possession or is otherwise available in the public domain). If the JSC does not agree to allow the [\*] to proceed under the GDP and the other Party raises any of the concerns set forth in subclauses (i), (ii), or (if such proposed [\*] would occur prior to [\*] of the applicable Licensed Product) (iii) above, then the [\*] shall discuss and determine whether or not such new [\*] should be permitted to proceed under the Right to Combine Mechanism. If the [\*] do not agree within [\*] after the matter has been escalated to the [\*], the non-proposing Party shall have the [\*]. If such [\*] proceeds and results in, or the data from

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such new Clinical Study is used in a [\*] for the Licensed Product in the Field, then such approved [\*] will be included in the applicable GCP and Commercialized by both Parties pursuant to the applicable GCP, and the related Manufacturing Costs, Medical Affairs Costs and Commercialization Costs for such Licensed Product in such new [\*] excluding for the avoidance of doubt, Manufacturing, Medical Affairs and Commercialization costs for any [\*]) shall [\*]. In no event shall: [\*]

## 6.5 Development Efforts; Manner of Performance; Reports

#### 6.5.1 Development efforts.

- (A) <u>Diligence</u>. With respect to the activities that have been assigned to a Party under the GDPs and GMAPs, such Party shall use Commercially Reasonable Efforts (as further described in clause 6.5.1(B) below) to execute and to perform, or cause to be performed, the activities assigned to it in the GDPs and GMAPs (including all applicable activities agreed by the Parties to be assigned to it under the Development Manufacturing and Supply Plans which are incorporated into the GDP) and any related plans under this Agreement, and to cooperate with the other Party in carrying out such plans, in accordance with the timetables and budgets therein.
- (B) Commercially Reasonable Efforts. The Parties agree that, as of the Effective Date, for purposes of determining what [\*] for the Development of the [\*] Product, a "[\*]" as used in the [\*], to the [\*] Product shall be deemed to be [\*] that is a [\*], and the term Commercially Reasonable Efforts, as used in clause 6.5.1(A), shall be construed accordingly for the Development of the [\*] Product. During the Term, the Parties shall, from time to time, jointly reassess whether or not such [\*] criteria should still apply to the [\*] Product, for the purposes of determining [\*].
- (C) [\*]. Licensee further agrees that the [\*] for the [\*] Product set forth on Schedule 8, as well as Clinical Study [\*], shall (i) be recognized and treated as [\*] Clinical Studies, and (ii) shall have the [\*] that a Clinical Study can achieve within [\*], in each case ((i) and (ii)) as of the Effective Date. All [\*] in respect of Non-[\*] Products will be reviewed and assessed by Licensee for [\*] as [\*] Clinical Studies within [\*] on a quarterly basis and [\*] shall report on such review and assessment at each JDC meeting as a standing agenda item. If requested to do so by [\*] shall provide a reasonably detailed explanation, no more than semi-annually, to the JDC as to whether any such [\*] qualify for [\*] status [\*] at the time of such explanation. If the JDC mutually agrees that any [\*] that did not previously qualify for [\*], or any [\*] should be considered for a [\*] status, if applicable, then [\*] shall reasonably [\*] for conferring such [\*] upon such [\*] to [\*], at the next reasonably available opportunity based on its [\*].
- 6.5.2 Each Party and its Affiliates shall conduct its Development activities in good scientific manner and in compliance with applicable Law, including Laws regarding environmental, safety and industrial hygiene, and Good Laboratory Practice, Good Manufacturing Practice, Good Clinical Practice, informed consent and Institutional Review Board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects. Notwithstanding anything to the contrary contained herein, if a Party reasonably determines that performance of a particular Development activity for a Licensed Product would violate

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applicable Law or pose an unacceptable safety risk for subjects participating in such Clinical Study, then it shall so notify the other Party, and the JDC shall discuss such notifying Party's concerns in good faith to determine whether to terminate, suspend, modify or continue such Development activity. If the Parties are unable to reach agreement with respect to whether to terminate, suspend, modify or continue such activity, the matter shall be resolved by the JSC and if the JSC is unable to resolve such matter it shall be resolved in accordance with clause 17.

- 6.5.3 <u>Day-to-Day Responsibility</u>. Each Party shall be responsible for day-to-day implementation of the Development activities for which it (or its Affiliate) has, or otherwise is assigned, responsibility under this Agreement or the GDPs and shall keep the other Party reasonably informed as to any material updates regarding such activities, as determined by the JDC.
- 6.5.4 <u>Development Reports</u>. At each meeting of the JDC, the Parties will jointly report on the Development activities they (and their Affiliates and Subcontractors) have performed or caused to be performed since the last meeting of the JDC pursuant to the GDP. The level of detail to be provided in such reports shall be determined by the JDC. If a Party fails to adequately provide such report at a meeting of the JDC, at the other Party's request, such Party shall provide a detailed written progress report that includes information regarding accrual, site initiation, progress on protocol writing, meeting requests and briefing documents, in the case of clinical or regulatory activities.
- 6.5.5 Compliance Audits. With respect to any facility or site at which a Party or its Affiliates conducts Development activities pursuant to this Agreement or the GDPs, the other Party shall have the right, at its expense, upon reasonable written notice to the such Party (and if applicable, such Affiliate), and during normal business hours, to inspect such site and facility and any records relating thereto [\*], to verify the other Party's (including its Affiliates') compliance with the terms of this Agreement and applicable Law, including Good Laboratory Practices, Good Manufacturing Practice, Good Clinical Practices and SOPs in respect of such Development activities. Such inspection shall be subject to the confidentiality provisions set out in clause 14. With respect to any facility or site at which a Party's Subcontractor conducts Development activities pursuant to this Agreement or the GDPs, to the extent such Party's contract or other written agreement with such Subcontractor includes a clause permitting such Party to inspect such site and facility and any records relating thereto, such Party shall exercise such inspection right under such agreement at the other Party's reasonable request to the extent such right is available at the time of such request, and such request shall not be made by the other Party more than [\*] (or such lesser frequency as set forth in such agreement with such Subcontractor). Following the completion of such inspection, the subcontracting Party shall provide the requesting Party a written summary of such inspection, to the extent such summary can be provided without violating any confidentiality obligations owed to such Subcontractor under any applicable written agreement. The requesting Party shall (to the extent reasonably possible) have the right to have [\*] present at such inspection.
- 6.5.6 Quality Assurance Audits. Each Party shall be responsible for establishing audit plans for each Clinical Study assigned to it in the GDPs according to its internal SOPs. The JDC (or its chosen Subteam) shall review and provide comments on the audit plans established by Licensee and Genmab's quality assurance personnel. Licensee and Genmab's quality assurance personnel will each consider in good faith all such comments submitted by the Joint Regulatory Subteam, but Licensee and

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- Genmab's quality assurance personnel shall each have final decision-making authority with respect to the audit plans it develops.
- 6.5.7 <u>Development Standards</u>. The JDC may establish standards and key performance indicators applicable to the Parties' (and their Affiliates' and Subcontractors') performance of Development activities in accordance with the GDPs and this Agreement. The Parties may review and discuss each Party's (and its Affiliates' and Subcontractors') performance against such standards and key performance indicators at each meeting of the JDC. [\*].
- 6.6 Regulatory Submissions and Regulatory Approvals
- 6.6.1 Regulatory Responsibilities. The Parties shall [\*], through their participation in the Joint Regulatory Subteam, be responsible for seeking and attempting to obtain all Regulatory Approvals for the Licensed Products in the Field in the Territory in accordance with the GDPs and GMAPs.
- 6.6.2 Ownership of Regulatory Approvals. Subject to clauses 6.6.3 and 7.7.1 below, [\*] in connection with the Development activities set out in the GDPs, the marketing and sale of the Licensed Products set out in the GCP and the Medical Affairs activities set out in the GMAP. [\*] in connection with the Development activities set out in the GDPs, the Medical Affairs activities set out in the GMAP and the marketing and sale of the Licensed Products set out in the GCP.
- Subject to applicable Law, [\*] shall have the right to participate in the 6.6.3 Regulatory Cooperation. Regulatory Filing and Regulatory Approvals submitted and owned by [\*] by having at least [\*] representative present at all material meetings, conferences and discussions by [\*] or its Affiliate with Regulatory Authorities pertaining to Development of the Licensed Products in the Field or Regulatory Approval. [\*] shall provide [\*] with reasonable advance notice of all such meetings and other contact and advance copies of all related documents and other relevant information relating to such meetings or other contact for the [\*] to review and comment on. [\*] shall provide the JRS with advance drafts of any material documents or other material correspondence pertaining to Regulatory Approvals, including any proposed labelling, [\*] plans to submit to any Regulatory Authority. The JRS shall (A) [\*] and (B) [\*]. [\*] may submit any such Regulatory Filing to a Regulatory Authority in the Territory without [\*]. In the event that the JRS is unable to agree, such matter shall be referred to the JSC for approval. If the JSC is unable to agree such matter, [\*] (which, for the avoidance of doubt, in each case shall not be subject to challenge, review or arbitration). [\*] shall provide the JRS with copies of all material submissions it makes to, and all material correspondence it receives from, a Regulatory Authority pertaining to a Regulatory Approval. Notices, copies of submissions and correspondence, and other materials to be given in advance shall be provided at least [\*] in advance unless circumstances necessitate a shorter time period, and in any event not less than a reasonable time in advance under the circumstances. Each Party shall support the other Party, as may be reasonably necessary or appropriate, in obtaining Regulatory Approvals for the Licensed Products in accordance with the responsibilities allocated to such Parties under clause 6.6.2, including by providing necessary documents or other materials required by applicable Law or by request of any Regulatory Authority.
- 6.6.4 Rights of Reference and Access to Data. Each Party shall have the right to cross-reference the other Party's or its Affiliate's drug master file, if any, and any other

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Regulatory Filings anywhere in the world related to the Licensed Products, and to access such Regulatory Filings and any Data and Know-How therein and use such Data and Know-How solely in connection with the performance of its obligations and exercise of its rights under this Agreement in accordance with the Data Protection Agreement, including inclusion of such Data and Know-How in its own Regulatory Filings for the Licensed Products. Each Party hereby grants to the other Party a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent exclusive right of access/reference in any other country or region in the Territory, to any Data, including such Party's or its Affiliate's clinical dossiers, Controlled by such Party or such Affiliate that relates to the Licensed Products for use by the other Party to Develop, Manufacture and Commercialize the Licensed Products in the Field pursuant to this Agreement. Each Party or such Affiliate shall provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any country or region of the Territory or otherwise provide appropriate notification of such right of the other Party to the applicable Regulatory Authority.

Regulatory Authority inspections. The Parties shall cooperate in good faith with respect to Regulatory 6.6.5 Authority inspections of any site or facility where Clinical Studies or Manufacturing of the Licensed Products in the Field are conducted by or on behalf of a Party pursuant to this Agreement, whether such site or facility is such Party's or its Affiliate's or Subcontractor's (each an "Audited Site"). Each Party shall be given a reasonable opportunity (taking into account the timing and notice provided by the applicable Regulatory Authority) to assist in the preparation of the other Party's Audited Sites for inspection, where appropriate and reasonably practicable, and (to the extent reasonably practicable) to attend any inspection by any Regulatory Authority of the other Party's Audited Sites, and the summary, or wrap-up, meeting with a Regulatory Authority at the conclusion of such inspection. If such attendance would result in the disclosure to the other Party of Confidential Information unrelated to the subject matter of this Agreement, the Parties shall enter into a confidentiality agreement covering such unrelated subject matter, and the non-audited Party shall make reasonable accommodations to limit such nonaudited Party's exposure to such other Party's Confidential Information. If any Audited Site is found to be non-compliant with one or more Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice or current standards for pharmacovigilance practice, the non-compliant Party shall submit to the other Party a proposed recovery plan or Corrective and Preventative Actions ("CAPA") within [\*] (or such other period as the Parties may agree) after such non-compliant Party, its Affiliate or its Subcontractor receives notification of such non-compliance from the relevant Regulatory Authority and such noncompliant Party shall use Commercially Reasonable Efforts to implement such recovery plan or CAPA promptly after submission. Each Party agrees, to the maximum extent possible, to include in any contract or other written arrangement with its Subcontractors, a clause permitting the other Party to exercise its rights under this clause 6.6.5.

# 6.7 **Patient Samples**

All patient samples (such as tissue samples) collected and retained in connection with Clinical Studies performed under this Agreement, including any Clinical Studies performed under the GDPs or post-Regulatory Approval Commercialization studies (but excluding any Clinical Studies performed pursuant to: (i) the Right to Proceed Mechanism (unless payment has been made in respect of the relevant Clinical Study performed under the Right to Proceed Mechanism pursuant to clause 6.3.2); or (ii) the

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Right to Combine Mechanism) (together with compilations of Data comprising annotations, or correlating outcomes, with respect to such samples, "Patient Samples") shall be used by each Party solely in the performance of its obligations under this Agreement and any GDP, GCP or GMAP. Unless otherwise agreed by the Parties, all Patient Samples shall be maintained and stored at the facilities of a Third Party selected by the JDC, and the fees paid to such Third Party in connection with such maintenance and storage shall be [\*] during the Term (and after the Term, shared equally by the Parties). Each Party shall access the Patient Samples, and authorize Affiliates and Third Parties to access the Patient Samples, in each case solely to the extent in accordance with the applicable GDP, GCP, GMAP or as otherwise approved by the JDC (or, following termination or expiration of this Agreement, as approved by the Parties) in advance in respect of the Licensed Product. Each Party shall promptly provide the other Party with: (a) all Data made, generated or obtained in whole or part through use of the Patient Samples in accordance with the terms of the Data Protection Agreement, whether during or after the Term, and (b) all Know-How made, generated or obtained in whole or part through use of the Patient Samples, whether during or after the Term (and such Know-How made, generated or obtained during the term in respect of the Licensed Products, and any Patent Rights in and to any inventions within such Know-How, shall constitute Collaboration Technology for purposes of clause 12.2).

## 6.8 Decisions to Terminate or Suspend a Study Based on Safety Concerns

- 6.8.1 Right of Sponsor. The Party sponsoring or controlling any Clinical Study of the Licensed Products (the "Sponsor") may terminate or suspend such Clinical Study, [\*], if a Regulatory Authority or safety data review board for such Clinical Study has required such termination or suspension. In such case, the Sponsor shall [\*].
- 6.8.2 Right of Sponsor and Non-Sponsor. If either Party believes in good faith that termination or suspension of a Clinical Study of the Licensed Products is warranted because of safety or tolerability risks to the study subjects, then such Party shall so notify the other Party and the Parties shall discuss the notifying Party's concerns in good faith to determine whether to terminate, suspend, modify or continue such Clinical Study. If the Parties are unable to reach agreement with respect to whether to terminate, suspend, modify or continue such Clinical Study, [\*].

#### 7. Commercialization

#### 7.1 Commercialization efforts

- 7.1.1 <u>JCC oversight</u>. The JCC shall oversee and have authority regarding all Commercialization of the Licensed Products in the Field in the Territory.
- 7.1.2 Commercialization principles. The Parties intend that Commercialization of the Licensed Products will be conducted in accordance with the following principles, and the JCC (or JSC, or the Executive Officers, as applicable) shall take into account and attempt to implement the following principles in its decision-making, including in the preparation, review and approval of all aspects of the Global Commercialization Plans and any updates to and amendments of such plans, and otherwise when allocating Commercialization responsibilities between the Parties in accordance with this Agreement:
  - (a) The JCC shall serve as a conduit for sharing information, knowledge and expertise relating to the Commercialization of the Licensed

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Products, and the principles of information-sharing about Commercialization of the Licensed Products in the Territory shall be reciprocal.

(b) The JCC's and JSC's roles in reviewing and approving the Territory Commercialization Plans included in the GCPs and any updates and amendments thereto, shall be consistent across all countries and regions.

#### 7.2 Global Commercialization Plans

#### 7.2.1 Global Commercialization Plans.

The Parties shall jointly develop, the JCC shall review, and the JSC shall review and approve, a Global Commercialization Plan for each Licensed Product which shall govern the Commercialization of such Licensed Product in the Field in the Territory. The Global Commercialization Plans shall include [\*] consolidated Net Sales forecasts and provide strategy for global Commercialization (such as global launch plans, country launch sequence and resourcing plans). The Global Commercialization Plans shall also include: (i) the applicable Global Commercialization Budget; (ii) the Territory Commercialization Plans for the applicable Licensed Product; (iii) the Territory Commercialization Budgets for the applicable Licensed Product; (iv) the Commercial Manufacturing and Supply Plan for the applicable Licensed Product in respect of activities after Regulatory Approval of that Licensed Product; and (v) the Global Pricing Strategy for each Licensed Product. The Global Commercialization Plans shall be updated at least annually as provided in clause 9.1. The initial Global Commercialization Plans shall be submitted to the JCC for review no later than [\*] prior to anticipated First Commercial Sale in the Territory, and submitted to the JSC for approval [\*] prior to anticipated First Commercial Sale in the Territory. The terms of and activities set out in the applicable Global Commercialization Plans shall at all times be designed to be in compliance with all applicable Laws and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry, taking into account where applicable each Party's healthcare compliance policies and applicable SOPs.

#### 7.2.2 Global Commercialization Budgets.

- (A) The Global Commercialization Budgets included in the GCPs shall set out the consolidated budgeted amounts for Commercialization Costs to be incurred throughout the Territory under those Global Commercialization Plans during the then-current [\*] and the [\*] thereafter, as well as a high-level estimate of such budgeted amounts for the [\*]. The GCP shall also include for both Parties a budget for global consolidated FTE Costs, PDE Costs and Out-of-Pocket Costs, broken down by [\*] for the [\*]. The Global Commercialization Budgets shall also include a breakdown of costs: (i) by functional area or category as determined by the JCC in conjunction with the JFS; and (ii) between consolidated Commercialization Costs incurred in respect of [\*] in [\*] and all other Commercialization Costs.
- (B) In reviewing and approving the Global Commercialization Budgets and any Substantive Amendment thereto, the JSC (or the Executive Officers if applicable) shall refer to and consider each Party's [\*]. It is understood that each Party's Commercialization Projection is a good faith projection only and is not binding or a guarantee by such Party that it will be able to successfully

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#### 7.2.3 Territory Commercialization Plans.

- The GCPs shall each include Territory Commercialization Plans setting out specific (A) Commercialization activities to be performed by the Parties in respect of each of the Licensed Products in the Field in specific countries in the Territory. The Territory Commercialization Plans shall be developed jointly by the Parties and form part of, and be incorporated into, the applicable GCP, and be reviewed by the JCC and approved by the JSC pursuant to clause 7.2.1, and be updated at least [\*] pursuant to clause 9.2, provided, however, that [\*], which plans for the avoidance of doubt shall still be reviewed by the JCC and approved by the JSC. The initial Territory Commercialization Plans shall be submitted to the JCC and JSC in accordance with the time periods set out in clause 7.2.1. The terms of, and activities set out in, the Territory Commercialization Plans shall at all times be designed to be in compliance with the GCP, all applicable Laws and to be conducted in accordance with the terms of this Agreement (including the principles set out in clause 7.1.2), professional and ethical standards customary in the pharmaceutical industry, taking into account where applicable the Parties' health care compliance policies and applicable SOPs (which shall be provided to the other Party upon request).
- The Territory Commercialization Plans for each Licensed Product shall include corresponding (B) Commercialization Budgets setting out the budaeted amounts Commercialization Costs for the activities set out in the respective Territory Commercialization Plans during the then-current [\*], as well as a high-level estimate of such budgeted amounts for the [\*]. Such Territory Commercialization Budgets shall include a budget for FTE Costs, PDE Costs and Out-of-Pocket Costs, broken down by [\*] for the then-current [\*]. Such Territory Commercialization Budgets shall also include a breakdown of costs by functional area or category as determined by the JCC in conjunction with the Joint Finance Subteam. Territory Commercialization Budgets shall form part of, and be incorporated into, the Global Commercialization Budget and shall be reviewed, approved and updated as described in clauses 7.2.1, 7.2.2 and 9.2. In reviewing and approving the Territory Commercialization Budgets as part of the GCP and any Substantive Amendment thereto, the JSC (or the Executive Officers if applicable) shall refer to and consider each Party's Commercialization Projection in accordance with clause 7.2.2(B).
- 7.2.4 Commercial Manufacturing and Supply Plan. The Parties shall jointly develop, with the JCMCS, Commercial Manufacturing and Supply Plans for each Licensed Product setting out the Manufacturing activities to be performed post-Regulatory Approval of the Licensed Product. Such Commercial Manufacturing and Supply Plans shall be incorporated into, and form part of, the GCP. Such Commercial Manufacturing and Supply Plans shall be reviewed and approved as part of the GCP as applicable pursuant to clause 7.2.1 and updated annually in accordance with procedures set out in clause 9.2. The terms of such Commercial Manufacturing and Supply Plans shall at all times be designed to be in compliance with the GCP, all applicable Laws and taking into account where applicable each Party's applicable SOPs.

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## 7.2.5 Global Pricing Strategy.

- (A) Prior to the Commercial launch of a Licensed Product, the JCC shall develop and incorporate into the GCP a global market access, pricing and reimbursement strategy for that Licensed Product, [\*] (each a "Global Pricing Strategy"), [\*].
- (B) [\*] pursuant to clause 7.7.1 shall, in close partnership and consultation with the other Party or its Affiliate, be responsible for [\*] for that Licensed Product in the Field [\*] in accordance with the Global Pricing Strategy and [\*].
- (C) [\*] shall, in close partnership and consultation with [\*], be responsible for obtaining [\*] for the Licensed Products in the Field [\*] in accordance with the agreed upon Global Pricing Strategy [\*].
- (D) [\*]

#### 7.3 Activities and Participation.

#### 7.3.1 Commercialization Efforts.

- (A) Each Party shall use Commercially Reasonable Efforts to execute and to perform, or cause to be performed, the activities agreed by the Parties to be assigned to it under the Global Commercialization Plans (including activities agreed by the Parties to be assigned to it under the Territory Commercialization Plans and Commercial Manufacturing and Supply Plans which are incorporated into the GCP) in accordance with applicable Law. In particular:
  - (a) with respect to the activities allocated by the Parties to each of them under the Territory Commercialization Plans for [\*] and [\*], unless agreed otherwise by the JCC, Genmab and Licensee shall use Commercially Reasonable Efforts to ensure that each Party [\*]. [\*].
  - (b) with respect to the activities allocated by the Parties to each of them under the Territory Commercialization Plans [\*].

Notwithstanding anything to the contrary contained herein, if a Party reasonably determines that performance of such Commercialization activity would violate applicable Law or pose an unacceptable safety risk to patients, then such Party shall so notify the other Party and the Parties shall discuss the notifying Party's concerns in good faith to determine whether to terminate, suspend, modify or continue such activity. If the Parties are unable to reach agreement with respect to whether to terminate, suspend, modify or continue such activity, [\*].

(B) Until Genmab exercises its option under clause 7.3.2, Genmab shall have the right to designate, at its discretion, up to three (3) representatives of Genmab (the "Genmab Representatives") per Licensed Product to [\*] strategic planning for, and to [\*], provided that Genmab Representatives shall not have the right to [\*] activities that relate to any products of Licensee that are not Licensed Products. [\*].

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(C) All Commercialization activities with respect to Licensed Products performed by each Party or its Affiliates in the Territory shall be in compliance with applicable Law, including all Health Care Laws and applicable standards for pharmacovigilance practice.

## 7.3.2 <u>Genmab opt-in for Commercialization in Territory B.</u>

## (A) Genmab Opt-In.

- (a) <u>Genmab Opt-In Right</u>. On a Non-[\*] Product-by-Non-[\*] Product and country-by-country basis, with respect to any Non-[\*] Product in any given country in [\*] and subject to the terms of this clause 7.3.2(A), Licensee hereby grants to Genmab the option for Genmab to undertake operational Commercialization activities for such Non-[\*] Product in such country (in addition to its existing involvement in strategic Commercialization activities for [\*]) (each such option, a "<u>Genmab Opt-In Right</u>").
- (b) <u>Designated Country Demonstration</u>. Genmab may exercise a Genmab Opt-In Right at any time at least [\*] prior to the anticipated Commercial launch of such Non-[\*] Product in such country by so notifying Licensee in writing, which notice shall include (i) reasonable evidence demonstrating that Genmab possesses sufficient expertise, resources and capabilities to conduct such co-Commercialization activities in such country, or (ii) a reasonable written plan describing the activities that Genmab plans to [\*] prior to the Commercial launch of such Non-[\*] Product in such country, then the Parties shall discuss in good faith any [\*] such Non-[\*] Product in such country, provided that such [\*].
- (c) Genmab Commercialization Activities Following Genmab Opt-In. Upon Licensee's receipt of any such notice, such country shall be deemed a "Designated Country" hereunder. From the date of such notice. Genmab shall have the right to perform co-Commercialization activities (including preparations for Commercial launch) in such Designated Country in respect of the relevant Non-[\*] Product(s) which are consistent with the Commercialization activities: (i) set out in the Territory Commercialization Plan for the Designated Country; and (ii) designated to Genmab in other Designated Countries, provided, however, on a Commercialization activity-by-Commercialization activity basis, if Genmab does not [\*] for such Non-[\*] Product in such Designated Country pursuant to sub-clause (b) above, then Genmab shall [\*]. Without limiting the foregoing, Genmab's exercise of any Genmab Opt-In Right is [\*]. Genmab may exercise a Genmab Opt-In Right in the manner described in this clause 7.3.2(A) with respect to each country and Licensed Product (excluding the [\*] Product) in [\*], provided, however, that Genmab may not exercise a Genmab Opt-In Right with respect to a given Licensed Product in a given country if it has previously [\*] for such Licensed Product in such country in accordance with clause 7.3.2(B). Following Genmab's exercise of a Genmab Opt-In Right, the JCC shall discuss in good faith any amendments which will be required to the Global Commercialization

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

- Plan(s) (including the Global Commercialization Budget(s)), the Territory Commercialization Plan(s) for [\*] or other applicable documents or plans to reflect such activities by Genmab in such Designated Country/ies in [\*], and present any Substantive Amendments to the JSC for approval.
- (B) [\*]. Following Genmab's exercise of its Genmab Opt-In Right, Genmab may, upon giving Licensee not less than [\*] prior written notice, [\*] on a [\*] (a "[\*]"). Upon the effective date of such written notice (which shall occur on the date specified in such notice but not less than [\*] from the date of Licensee's receipt of such notice), [\*] Genmab's obligation to perform Commercialization activities for such Licensed Product in such country [\*], and Genmab [\*] for such Licensed Product in such country again. For the avoidance of doubt, such termination shall not affect Genmab's rights under clauses 8 or 11.3.

## 7.4 Manner of performance

- 7.4.1 <u>Day-to day responsibility</u>. Each Party shall be responsible for day-to-day implementation of the Commercialization activities with respect to the Licensed Products for which it has, or otherwise is assigned, responsibility under this Agreement and the Global Commercialization Plans, and shall keep the other Party reasonably informed as to the progress of such activities, as determined by the JCC.
- 7.4.2 Commercialization standards. The JCC shall establish standards applicable to the Parties' performance of Commercialization activities in the Territory in accordance with the Global Commercialization Plans and this Agreement, which shall include standards for sales Field Based Representatives promoting Licensed Products in the Field. The Parties shall review and discuss each Party's (and its Affiliates', Subcontractors' and sublicensees) performance against such standards in Territory A, each Designated Country and the [\*] at each meeting of the JCC. If the JCC determines that a Party or its Affiliate or Subcontractor or sublicensee has failed to comply with such standards and such failure could adversely affect the Commercialization of any Licensed Products in the Field, or if the JCC does not agree and one Party believes such is the case, the JCC shall (or such Party may) so notify the JSC and the JSC shall discuss whether any remedial action is desirable.
- 7.4.3 Commercialization reports. At each meeting of the JCC, the Parties will jointly report on the Commercialization activities they (and their Affiliates and Subcontractors and sublicensees) have performed or caused to be performed in the Territory with respect to the Licensed Products since the last meeting of the JCC. The level of detail to be provided in such reports shall be determined by the JCC, [\*]. If a Party fails to adequately provide such report, at the other Party's request, such Party shall provide a written progress report that describes in reasonable detail the Commercialization activities that such Party has performed or caused to be performed since the last meeting of the JCC. The JCC shall update the JSC at each [\*] meeting of the JSC of the Commercialization activities of the Parties in the preceding [\*].

# 7.5 Advertising and promotional materials

7.5.1 <u>Global Brand Plans</u>. The Parties shall jointly develop plans for the promotion of the Licensed Products throughout the Territory, including brand guidelines for the use of any Licensed Product Trademarks (the "<u>Global Brand Plans</u>").

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- 7.5.2 Promotional materials. Promotional materials for the Licensed Products for use in: (i) [\*]; or (ii) in [\*] shall be developed jointly by the Parties. Such promotional materials shall be strategically aligned with the Global Brand Plans, the Parties' compliance SOPs, applicable Laws and Regulatory Approvals. All such promotional materials shall be reviewed by both Parties through a joint medical and promotional compliance process (including legal review) to be established by the Parties at least twelve (12) months before the anticipated First Commercial Sale of any Licensed Product and copies of such materials shall be archived by the Parties in accordance with applicable Laws. Promotional materials to be used in all other countries and territories in the Territory shall be developed by Licensee and be strategically aligned with the Global Brand Plans, Licensee's compliance SOPs, applicable Laws and Regulatory Approvals. Copies of all promotional materials used by Licensee and its Affiliates in such other countries and territories for the Licensed Products shall be shared with Genmab and archived by Licensee in accordance with applicable Laws.
- 7.5.3 If a Party reasonably considers that any promotional materials developed pursuant to clause 7.5.2 would breach, or otherwise does not comply with, applicable Laws or Regulatory Approvals, it shall promptly notify the other Party of the same. If the other Party disputes such breach or non-compliance, the matter shall be referred to the JCC for resolution and, pending resolution, the concerned Party shall not be obliged to use such promotional materials.

## 7.6 Licensed Products packaging

- (A) On a Licensed Product-by-Licensed Product and country-by-country basis, the Party who owns all Regulatory Filings and Regulatory Approvals for a given Licensed Product in a given country pursuant to clause 6.6.2 shall develop the packaging for such Licensed Product for use in such country, provided that such Party shall consider in good faith any comments provided by the other Party with respect to such packaging. Such packaging shall be compliant with the Global Brand Plans, each Party's applicable SOPs, the Global Commercialization Plans and applicable Laws and Regulatory Approvals.
- (B) In those countries in the Territory where the Parties are co-Commercializing the Licensed Products, the Licensed Products packaging shall (to the extent permitted by Law and subject to approval by the Regulatory Authorities) include the corporate names and logos of both Parties in equal prominence.
- (C) In those countries in the Territory where only one Party is Commercializing the Licensed Products, the Licensed Products packaging shall (to the extent permitted by Law and subject to approval by the Regulatory Authorities) include the corporate name and logo of that Party.

# 7.7 Sales and distribution

7.7.1 Territory A - Booking sales. Genmab and its Affiliates shall book all sales of the [\*] Product in Territory A. Responsibility for booking sales of all other Licensed Products in Territory A shall [\*], such that (A) [\*] and its Affiliates shall book all sales of the [\*] Licensed Product (other than the [\*] Product) for which there is a First Commercial Sale in any country in Territory A, (B) [\*] and its Affiliates shall book all sales of the [\*] Licensed Product after the Licensed Product referred to in (A) for which there is a First Commercial Sale in any country in Territory A, [\*]. To the extent not inconsistent with any other provision in this Agreement, the allocation of responsibilities and

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activities under the Global Commercialization Plans shall be made in a manner that permits the applicable booking Party (pursuant to the foregoing sentence of this clause 7.7.1) to book all sales of the applicable Licensed Product in Territory A in accordance with GAAP. If a non-booking Party receives any orders for a Licensed Product in Territory A, then it shall refer such orders to the booking Party. Notwithstanding any provision in this Agreement to the contrary, rights accorded to Genmab under clauses 6 and 7 in its capacity as the entity booking sales for a Licensed Product in Territory A shall be deemed to refer to Licensee in those circumstances where Licensee is the entity booking sales for that Licensed Product in Territory A pursuant to this clause (and rights accorded to Licensee under clauses 6 and 7 in its capacity as the entity not booking sales for a Licensed Product in Territory A shall be deemed to refer to Genmab in those circumstances where Genmab is the entity not booking sales for that Licensed Product in Territory A pursuant to this clause).

7.7.2 <u>Territory B - Booking sales</u>. Licensee and its Affiliates shall book all sales of the Licensed Products in Territory B. For the avoidance of doubt, if Genmab exercises its right under clause 7.3.2, the Parties shall ensure that the allocation of responsibilities and activities under the Global Commercialization Plans shall be made in a manner that permits Licensee to continue to book all sales of the Licensed Products in Territory B in accordance with GAAP. If Genmab receives any orders for a Licensed Product in Territory B, it shall refer such orders to Licensee.

## 7.8 Sharing of commercial information

The Parties and their Affiliates will actively collaborate as set out in this Agreement in the Commercialization of the Licensed Products in the Field in the Territory, and, to the extent necessary or reasonably useful to the other Party to support such Commercialization activities and subject to clause 14, each Party will [\*].

## 7.9 Other responsibilities

- 7.9.1 [\*]. Other than with respect to the disposition of Licensed Products in Licensee's, or Genmab's or in their respective Affiliates' possession (as applicable): (A) [\*] pursuant to clause 7.7.1 shall also be responsible for handling all returns of the Licensed Products in [\*], and if a Licensed Product sold in [\*] is [\*] to [\*], [\*] shall promptly ship such Licensed Product to a facility designated by [\*]; and (B) [\*] shall also be responsible for handling all aspects of the applicable Licensed Product's order processing, invoicing and collection, distribution, inventory and receivables in [\*]. If [\*] is the [\*] it may use [\*] and [\*] Affiliates' distribution and storage facilities in connection with the performance of [\*] Commercialization activities in accordance with the terms of a distribution agreement to be entered into by the Parties at least [\*] prior to the First Commercial Sale of the applicable Licensed Product and in accordance with applicable Laws.
- 7.9.2 [\*]. [\*] shall be responsible for handling [\*] of the Licensed Products in [\*], and if a Licensed Product sold in [\*] is [\*] to [\*], [\*] shall promptly ship such Licensed Product to a facility designated by [\*]. [\*] shall also be solely responsible for handling all aspects of the Licensed Products order processing, invoicing and collection, distribution, inventory and receivables in [\*] and in accordance with applicable Laws.

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# 7.10 Adverse Event and Licensed Products Complaint Reporting Procedures; Notice of Information Affecting Marketability of the Licensed Products

- Pharmacovigilance. Within [\*] after the Effective Date, the Parties shall negotiate in good faith and enter into a pharmacovigilance agreement setting out the processes and procedures for sharing adverse event information and containing mutually agreed terms and conditions that are customary for agreements of this type (the "Pharmacovigilance Agreement"). Until execution of the Pharmacovigilance Agreement, the Parties shall, as soon as reasonably practicable, and in any event within [\*] after the Effective Date, implement a plan for prompt exchange of any and all information concerning adverse events related to use of the Licensed Products regardless of source, including timely notice of adverse events and serious adverse effects in order to permit each Party to comply with applicable reporting requirements. The Parties shall jointly agree the global strategies for, and content of, periodic reporting to applicable Regulatory Authorities. Each Party shall be responsible for any Clinical Study sponsored by it, or any marketing authorization for which it is the marketing authorization holder, for submitting: (i) adverse event and other safety reports to the applicable Regulatory Authority, including annual safety reports, periodic update safety reports and quarterly line listings; and (ii) adequate safety reports to the Clinical Study sites participating in such Clinical Study. If Genmab is such sponsor or marketing authorization holder, such reports shall be drafted by Licensee as holder of the global safety database and provided to Genmab at least [\*] in advance of their required date of submission; and if Licensee is such sponsor or marketing authorization holder, it shall be responsible for drafting and submitting to the applicable Regulatory Authorities such reports in respect of the Licensed Product.
- 7.10.2 Global safety database. No later than [\*] prior to the filing of an IND for a Licensed Product anywhere in the world or, if an IND has already been filed, [\*] after the Effective Date, Licensee shall establish the global safety database for Licensed Products. Licensee shall maintain a global safety database of adverse events and pregnancy reports for such Licensed Products, which shall be used for regulatory reporting and responses to safety queries from Regulatory Authorities by both Parties. Genmab shall, and shall cause its Affiliates to, transfer all adverse events information in its or their possession or control to the global safety database within a mutually agreed period of time that provides Licensee with sufficient time to enter all of the data and to obtain validation of the database, and Licensee shall use Commercially Reasonable Efforts to enter data from all adverse events information in its possession or control into the global safety database. Licensee shall provide Genmab with access to an identical copy of such global safety database.

#### 7.11 Recalls, Market Withdrawals or Corrective Actions

If a Regulatory Authority issues or requests a recall or takes a similar action in connection with any of the Licensed Products in the Territory, or if either Party determines (acting reasonably and in good faith) that an event, incident or circumstance has occurred which results in reasonable grounds for believing that there may be an actual or suspected defect with a Licensed Product such that a recall or market withdrawal in the Territory may be required, the Party notified of such recall or similar action, or the Party that believes such recall or similar action is required, shall within [\*], advise the other Party thereof by telephone or email. The Parties shall discuss and agree (acting reasonably and in good faith) whether to conduct a recall in one (1) or more countries in Territory A or Territory B (as applicable) and the manner in which any such recall shall be conducted, provided, however, in the event of a

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Regulatory Authority-mandated recall, Genmab (in respect of [\*]) and Licensee (in respect of [\*]) may act without such advance notice but in any event shall notify the other Party as soon as reasonably possible. In either case, if the Parties cannot agree as to whether a recall is required in the Territory, [\*] shall have final decision-making authority with respect to such matter (which shall not be subject to challenge, review or arbitration). Each Party will make available to the other Party, upon request, all of such Party's (and its Affiliates' and Subcontractors' and sublicensees') pertinent records that such other Party may reasonably request to assist such other Party in effecting any recall. The costs and expenses of any such recall shall be taken into account in determining Pre-Tax Profit or Loss as, and to the extent, provided in Schedule 10.

## 7.12 Early Access Programs

Genmab and Licensee may undertake Early Access Programs for the Licensed Products in the Field in [\*] and Licensee (and, if Genmab exercises its rights under clause 7.3.2, Genmab) may undertake Early Access Programs for the Licensed Products in the Field in [\*]. If either Party desires to undertake an Early Access Program in accordance with this clause 7.12, such Party shall submit to the JMAS a proposal for such Early Access Program, which proposal shall include the clinical methodology, monitoring requirements and funding budgets for such Early Access Program. If the JMAS agrees to an Early Access Program proposal, such proposal shall be submitted to the JDC for review and to the JSC for approval. The JSC shall approve such Early Access Program proposal unless the JSC determines in good faith that the proposed Early Access Program could adversely affect the Development or Commercialization of the Licensed Products in the Field in Territory A or Territory B. The Parties' costs and expenses incurred in performing Early Access Programs that have been approved by the JSC in accordance with this clause 7.12 shall be taken into account in determining Shared Costs as, and to the extent, provided for in clause

## 7.13 Field Based Representatives

- 7.13.1 Each sales representative (including account executives and field access roles) used by a Party or its Affiliate to Detail the Licensed Products to healthcare professionals and each medical science liaison used by a Party or its Affiliate to provide disease information to healthcare professionals (each, a "Field Based Representative") pursuant to this Agreement shall be employed by such Party or one of its Affiliates as a member of its field force.
- 7.13.2 Genmab and Licensee shall each ensure that its and its Affiliates' Field Based Representatives shall only make representations and statements about the Licensed Products that are consistent with applicable Law, the current package insert of prescribing information or other documentation accompanying or describing a Licensed Products. Genmab and Licensee shall each ensure that its and its Affiliates' Field Based Representatives do not use any promotional materials other than those described in clause 7.5.
- 7.13.3 Genmab and Licensee shall ensure its and its Affiliates' Field Based Representatives comply with applicable Laws, guidelines and codes of practice related to the performance of its Commercialization obligations hereunder, including the Drug Regulation Laws, and anti-bribery and corruption Laws.

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7.13.4 Each Party shall maintain records of its Field Based Representative activities and each Party shall allow representatives of the other Party to inspect such records upon request during normal business hours and upon reasonable prior notice.

#### 8. Costs

# 8.1 Cost Sharing

(A) <u>Development Costs</u>. Development Costs incurred during the Term by the Parties for any given Licensed Product in any given country shall be borne [\*].

## (B) Commercialization Costs.

- (a) Commercialization Costs incurred during the Term by the Parties in the Territory for any Non-[\*] Product shall be borne [\*].
- (b) Commercialization Costs incurred during the Term by the Parties in Territory A for the [\*] Product shall be borne [\*].
- (c) Commercialization Costs incurred during the Term by the Parties in Territory B for the [\*] Product shall be borne [\*].

### (C) Medical Affairs Costs.

- (a) Medical Affairs Costs incurred during the Term by the Parties prior to obtaining Regulatory Approval for any given Licensed Product in any given country shall be borne [\*], subject to clause 8.4.
- (b) Medical Affairs Costs incurred during the Term by the Parties after obtaining Regulatory Approval for any Non-[\*] Product in the Territory shall be borne [\*].
- (c) Medical Affairs Costs incurred during the Term by the Parties after obtaining Regulatory Approval for the [\*] Product in Territory A shall be borne [\*]
- (d) Medical Affairs Costs incurred during the Term by the Parties after obtaining Regulatory Approval for the [\*] Product in Territory B shall each be borne [\*].

# (D) EAP Expenses.

- (a) EAP Expenses incurred during the Term by the Parties in Territory A for any Licensed Products shall be borne [\*]
- (b) EAP Expenses incurred during the Term by the Parties for any Non-[\*] Product in Territory B shall be borne [\*]
- (c) EAP Expenses incurred during the Term by the Parties for the [\*] Product in Territory B shall be borne [\*]

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- (E) <u>Shared Licensed Products Liability Costs</u>. Shared Licensed Products Liability Costs incurred during the Term by the Parties in the Territory for any Licensed Product shall be borne [\*]
- (F) <u>Patent Costs</u>. Patent Costs incurred during the Term by the Parties in the Territory for any Licensed Product shall be borne [\*]

The costs described in (A) – (F) above shall collectively be referred to as the "Shared Costs" and shall be paid between the Parties in accordance with the reconciliation procedures set forth in clauses 8.2 and 8.3.

## 8.2 Costs Reports

Shared Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in this clause 8.2. Each Party shall calculate and maintain records of Shared Costs incurred by it and its Affiliates in accordance with procedures to be established by the Joint Finance Subteam. The procedures for monthly reporting of actual results, monthly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Shared Costs will be determined by the Joint Finance Subteam (the "Shared Costs Reconciliation Procedures"). Such procedures will provide the ability to comply with financial reporting requirements of each Party. The Shared Costs Reconciliation Procedures shall provide that [\*] after the end of each [\*], each Party shall submit to the Joint Finance Subteam and the JSC a report, in such reasonable detail and format as is established by the Joint Finance Subteam, of all Shared Costs incurred by such Party during such [\*]. Within [\*] days following the receipt of such report, each Party shall have the right to request reasonable additional information related to the other Party's and its Affiliates' Shared Costs during such [\*] in order to confirm that such other Party's spending is in conformance with the approved Global Development Budgets, Global Commercialization Budgets, Territory Commercialization Budgets or other applicable budgets. The Joint Finance Subteam shall establish reasonable procedures for the Parties to share estimated Shared Costs for each [\*] within [\*] of the end of such [\*], to enable each Party to appropriately accrue its share of Shared Costs for financial reporting purposes.

#### 8.3 Reimbursement of Shared Costs

(A) Subject to clause 8.4, if a Party (with its Affiliates) incurs more than its budgeted share of the total actual Shared Costs for the Licensed Products ("Excess Amounts"), provided that: (1) the JSC approves such Excess Amounts (either before or after they are incurred), which approval shall not be unreasonably withheld to the extent such Excess Amounts were not within the reasonable control of the Party (or Affiliate) incurring such expense; or (2) to the extent such Excess Amounts do not exceed more than [\*] of the total Shared Costs allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year-to-date period in accordance with the approved Global Development Budgets, Global Commercialization Budgets, Territory Commercialization Budgets or other applicable budgets for such Calendar Year, the other Party shall pay such incurring Party an amount of cash sufficient to reconcile to its agreed percentage of actual Shared Costs in each [\*]. Such payments shall be made to the bank accounts set out in Schedule 10. Each Party shall promptly notify the other Party if it anticipates that it will incur Excess Amounts and the likely total amount of such Excess Amounts.

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- (B) The Shared Costs Reconciliation Procedures shall provide for the Joint Finance Subteam to develop a written report setting forth in reasonable detail the calculation of any net amount owed by Genmab to Licensee or by Licensee to Genmab, as the case may be, as necessary to accomplish the sharing of Shared Costs in the percentages set out in clause 8.1, and to prepare such report promptly following delivery of the report described in clause 8.2 and in a reasonable time (to be defined in the Reconciliation Procedures) in advance of payment. The net amount payable to accomplish the sharing of Shared Costs as provided under this Agreement shall be paid by Licensee or Genmab, as the case may be, within [\*] after the end of the applicable [\*]. In establishing the Shared Costs Reconciliation Procedures, the Joint Finance Subteam shall work to coordinate and harmonize all Reconciliation Procedures to permit for reconciliation, and associated payments, with respect to Shared Costs as well as Pre-Tax Profit or Loss within [\*] after the end of the applicable [\*].
- (C) In no event shall any amendment to the GDPs or Global Commercialization Plans (including any Territory Commercialization Plans and Manufacturing and Supply Plans incorporated therein) result in any Shared Costs exceeding the percentages and amounts listed in clause 8.1.

#### 8.4 [\*]

Notwithstanding clauses 8.1(A), 8.1(C)(a) and 8.3, in no circumstances shall [\*] under clauses 8.1(A) and 8.1(C)(a) (excluding, for clarity, any costs or expenses incurred in connection with Genmab's exercise of the Right to Proceed Mechanism or Right to Combine Mechanism pursuant to clauses 6.3 and 6.4) [\*] per Calendar Year per Licensed Product [\*]. Subject to the remainder of this clause 8.4, any [\*] for such Calendar Year in [\*] shall be [\*] and the reimbursement calculations set forth in clause 8.3 shall be adjusted accordingly. [\*] reimburse [\*] for an amount equal to [\*] by way of [\*], in each case, following the date on which [\*] incurs such [\*], which [\*] shall continue until such amounts incurred [\*] (but within [\*]) have been [\*] in [\*], provided that in no event shall such [\*] (as applicable) by more than [\*] in any [\*]. Notwithstanding the foregoing, Genmab may, at any time and in its sole discretion, elect to pay any portion of the outstanding amount owed by it to Licensee by way of an additional direct payment from Genmab to Licensee.

## 9. Amendments and updates to the GDP, GCP and GMAP

## 9.1 Updating and amending GDPs

(A) The JDC shall review the GDPs not less frequently than annually and shall develop detailed and specific amendments to update the GDPs. The JDC shall submit such annually updated GDPs (including the Global Development Budgets) for the following Calendar Year to the JSC for review and approval, such that JSC preliminary approval would occur no later than [\*] of each Calendar Year. Upon the JSC's preliminary approval, such updated GDPs (including the Global Development Budgets) shall be submitted to each Party for its internal budgeting process with a target for final approval of the updated GDPs (including the Global Development Budgets) by the JSC no later than [\*] of each Calendar Year, at which time all updates shall be appended to the GDPs. The JDC may also develop and submit to the JSC from time to time other proposed Substantive Amendments to the GDPs, including amending

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the existing GDPs or creating a new GDP to reflect the inclusion of an Option Compound as a new Licensed Compound as agreed by the Parties pursuant to the Research and Collaboration Agreement. The JDC shall also review each Party's (and its Affiliates') performance under the then-current GDPs (including the Global Development Budgets) on a quarterly basis, and shall develop detailed and specific amendments to the Global Development Budgets that reflect such performance. The JSC shall review any proposed Substantive Amendments presented by the JDC and may approve such proposed Substantive Amendments or any other proposed Substantive Amendments or any other proposed Substantive Amendments that the JSC shall consider from time to time in its discretion and, upon such approval by the JSC, the GDPs shall be amended accordingly. Substantive Amendments to the GDPs, including the Global Development Budgets, shall not be effective without the approval of the JSC (or the Executive Officers, as applicable). If the JSC does not approve an annual update or Substantive Amendment to the GDPs, including the Global Development Budgets, prior to the start of the next Calendar Year, [\*]. An amendment which is not a Substantive Amendment may be approved by the JDC and shall not require JSC approval to be binding.

Schedule 12 includes a high-level forecast of anticipated budget amounts and associated (B) timelines for Development of the Licensed Products. In reviewing and approving annual updates to the Global Development Budgets, the JSC (or the Executive Officer, if applicable) shall consider the budget amounts and timelines reflected in Schedule 12. Until total overall Development Costs of the Licensed Products reflected in Schedule 12 have been spent on the Development of the Licensed Products pursuant to this Agreement, the Global Development Budgets shall provide for at least the amounts reflected for the relevant year in Schedule 12 as of the Effective Date (or, if different, the amounts forecast for the relevant year in the most recently approved Global Development Budgets, taking into account any amounts actually spent for the years covered by such Global Development Budgets that have already occurred), on approximately the timelines set out in Schedule 12, unless the Parties otherwise agree or the JSC (or, if applicable, the Executive Officers) determines that spending such amounts on such timelines is not commercially reasonable for Development of the Licensed Products (viewing the Licensed Products on a stand-alone basis and not taking into account, for example, either Party's own portfolio management considerations).

## 9.2 Updating and amending Global Commercialization Plans

- (A) Each Calendar Year, the Parties shall develop and submit to the JCC for review, updated Global Commercialization Plans (including updated Global Commercialization Budgets, Territory Commercialization Plans, Territory Commercialization Budgets, and Commercial Manufacturing and Supply Plans).
- (B) The JCC shall submit such updated Global Commercialization Plans to the JSC for review and approval in time to permit the JSC's preliminary approval to occur no later than [\*] of the prior Calendar Year. Upon the JSC's preliminary approval of such updated GCPs, such plans shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC no later than [\*] of the prior Calendar Year, and after final approval by the JSC, such Global Commercialization Plans shall take effect on the first

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calendar day of the Calendar Year to which such Global Commercialization Plans apply.

- (C) The JCC shall review each Party's (and its Affiliates' and Subcontractors' and sublicensees') performance under the Global Commercialization Plans (and the relevant budgets included therein) on a [\*] basis, and shall develop detailed and specific amendments to the Global Commercialization Plans to reflect such performance. The JCC shall also reasonably consider any other proposed updates and amendments to the Global Commercialization Plans presented by either Party from time to time, including amending the existing Global Commercialization Plans or creating a new Global Commercialization Plan to reflect the inclusion of a new Licensed Product containing an Option Compound which is a new Licensed Compound as agreed by the Parties pursuant to the Research and Collaboration Agreement.
- (D) The JSC shall review any proposed Substantive Amendments to the GCP presented by the JCC and may approve such proposed Substantive Amendments or any other proposed Substantive Amendments that the JSC shall consider from time to time in its discretion and, upon such approval by the JSC, the Global Commercialization Plans shall be amended accordingly.
- (E) Substantive Amendments to the Global Commercialization Plans (including the budgets incorporated therein), shall not be effective without the approval of the JSC (or the Executive Officers if applicable).
- (F) If the JSC does not approve an annual updated GCP or Substantive Amendment to a Global Commercialization Plan (including the budgets incorporated therein), prior to the start of the next Calendar Year, either Party may initiate procedures to resolve the issue pursuant to clause 17, and the then-current Global Commercialization Plans (and the budgets incorporated therein) shall continue to apply until the Global Commercialization Plans are agreed by the JSC or the Executive Officers pursuant to clause 17.1, or determined by arbitration.
- (G) An amendment which is not a Substantive Amendment may be approved by the JCC and shall not require JSC approval to be binding.

## 9.3 Updating and amending Global Medical Affairs Plans

- (A) Each Calendar Year, the JMAS shall develop an updated Global Medical Affairs Plans (including updated Global Medical Affairs Budgets and Territory Medical Affairs Plans).
- (B) The JMAS shall submit such updated GMAPs to the JDC (with respect to any portion of the GMAP that pertains to Medical Affairs activities prior to Regulatory Approval of a Licensed Product) and JSC (with respect to any portion of the GMAP that pertains to Medical Affairs activities after Regulatory Approval of a Licensed Product) for review, and in each case they shall submit such updated GMAP to the JSC for approval in time to permit the JSC's preliminary approvals to occur no later than [\*] of the prior Calendar Year. Upon the JSC's preliminary approvals of such updated GMAPs, such plans shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC no later than [\*] of the prior Calendar

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Year, and after final approval by the JSC, such GMAPs shall take effect on the first calendar day of the Calendar Year to which such GMAPs apply.

- (C) The JMAS shall review each Party's (and its Affiliates' and Subcontractors' and sublicensees') performance under the GMAPs (and the relevant budgets included therein) on a quarterly basis, and shall develop detailed and specific amendments to the GMAPs to reflect such performance. The JMAS shall also reasonably consider any other proposed updates and amendments to the GMAPs presented by either Party from time to time, including amending the existing GMAPs or creating a new GMAP to reflect the inclusion of a new Licensed Product containing an Option Compound which is a new Licensed Compound as agreed by the Parties pursuant to the Research and Collaboration Agreement.
- (D) The JDC and JSC (as applicable) shall review any proposed Substantive Amendments to the GMAP presented by the JMAS and may submit such Substantive Amendments to the JSC for approval of those Substantive Amendments or any other proposed Substantive Amendments that the JDC and JSC (as applicable) shall consider from time to time in its discretion and, upon such approval by the JSC, the Global Medical Affairs Plans shall be amended accordingly.
- (E) Substantive Amendments to the Global Medical Affairs Plans (including the budgets incorporated therein), shall not be effective without the approval of the JSC.
- (F) If the JSC does not approve an annual updated GMAP or Substantive Amendment to a Global Medical Affairs Plan (including the budgets incorporated therein), prior to the start of the next Calendar Year, [\*].
- (G) An amendment which is not a Substantive Amendment may be approved by the JDC (with respect to any portion of the GMAP that pertains to Medical Affairs activities prior to Regulatory Approval of a Licensed Product) or JSC (with respect to any portion of the GMAP that pertains to Medical Affairs activities after Regulatory Approval of a Licensed Product) and shall not require further JSC approval to be binding.

## 10. Manufacture and supply

#### 10.1 Manufacture

- 10.1.1 <u>JSC and Subteam Oversight</u>. The JSC, in consultation with the JDC, JCMCS and the JFS, shall oversee and have authority regarding Manufacture of the Licensed Products and CMC Development in the Field, in the Territory.
- 10.1.2 [\*] Manufacturing. [\*] shall Manufacture: (i) the Licensed Products for clinical and (subject to clause 10.1.3) [\*] use, in accordance with the terms of the GDPs and GCPs. The Parties shall agree and enter into a supply agreement (one supply agreement per Licensed Product) in respect of [\*] Manufacture of clinical supplies of the respective Licensed Products ("Supply Agreement") as soon as reasonably practicable after the Effective Date. The Supply Agreements shall contain usual provisions relating to the supply and inventory of biopharmaceutical products (and the Parties' strategy with respect thereto) and shall be negotiated in good faith by the Parties taking into consideration the scope and effect of any corresponding supply

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obligations which Genmab may owe to its Manufacturing Subcontractor. Subject to clause 10.1.3, such Supply Agreements shall be amended or replaced (at the Parties' election) to address Manufacturing of commercial supplies of the respective Licensed Products in due course and in any event before the Manufacture of any Licensed Product for Commercialization.

10.1.3 Transfer of [\*]. The Parties acknowledge and agree that while the Development Manufacturing and Supply Plans shall [\*], it is intended that [\*] to be mutually agreed by the Parties. Prior to [\*] with respect to Licensed Products, the Parties shall agree and enter into a supply agreement in respect of [\*] which shall be broadly similar to the terms of the Supply Agreement, and the Supply Agreement shall expire.

Each Party shall use Commercially Reasonable Efforts to ensure a timely and effective [\*] with respect to the Licensed Products in accordance with the Development Manufacturing and Supply Plan or Commercial Manufacturing and Supply Plan (as applicable) and to complete the [\*] contemplated by this clause. [\*].

- 10.1.4 <u>Manufacturing performance</u>. The Parties may review and discuss each Party's (and its Affiliates' and Subcontractors') performance in respect of Manufacturing activities at each meeting of the JDC or JCC. If the JDC or JCC determines that a Party, or its Affiliate or Subcontractor has failed to comply with its Manufacturing obligations under the GDPs or GCPs as applicable and such failure could adversely affect the Development or Commercialization of the Licensed Products in the Field, or if the JDC or JCC does not agree and one Party believes such is the case, the JDC or JCC shall (or such Party may) so notify the JSC and the JSC shall discuss whether any remedial action is desirable.
- 10.1.5 <u>Costs</u>. For the avoidance of doubt, each Party's Manufacturing Costs incurred in connection with the Manufacture and supply of the Licensed Products hereunder shall [\*].

## 10.2 CMC Development

Allocation of responsibility to perform CMC Development for the Licensed Products shall be set out in the GDP. Each Party shall participate, through its representatives on the JDC, JCMCS and JFS, in decision-making with regard to CMC Development activities related to e.g. new formulations or dosage forms for the Licensed Products and of associated Manufacturing processes, which activities shall be conducted in accordance with the Development Manufacturing and Supply Plans or Commercial Manufacturing and Supply Plans incorporated into the GDP or GCP (as applicable).

#### 11. Financial provisions

# 11.1 Upfront payment

In partial consideration of the rights and licenses granted by Genmab to Licensee under this Agreement, Licensee shall pay to Genmab a non-refundable, non-creditable one-off payment of seven hundred fifty million U.S. Dollars (\$750,000,000) within [\*] after the Effective Date.

#### 11.2 Milestone payments

11.2.1 <u>Development Milestones</u>. In partial consideration for the rights and licenses granted by Genmab to Licensee under this Agreement, subject to clause 8.4 and clause

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11.2.4, Licensee shall pay, or cause to be paid, to Genmab each of the following non-refundable, non-creditable payments upon the achievement of each of the following milestone events (each a "<u>Development Milestone</u>") by or on behalf of the Parties or their Affiliates or sublicensees with respect to the applicable Licensed Products as described below in accordance with clauses 11.2.5 and 11.2.6.

Milestone event	Milestone Payment (\$USD)		
	GEN3013 Product	[*] Product	[*] Product
Initiation of a Pivotal Trial in the first Indication for a Licensed Product	\$40,000,000	[*]	[*]
[*]	[*]	[*]	[*]

Each Development Milestone shall be payable [\*] by each of [\*], respectively, to achieve such Development Milestone. [\*].

11.2.2 <u>Regulatory Milestones</u>. In partial consideration for the rights and licenses granted by Genmab to Licensee under this Agreement, subject to clause 8.4 and clause 11.2.4, Licensee shall pay, or cause to be paid, to Genmab each of the following non-refundable, non-creditable payments upon the achievement of each of the following milestone events (each a "<u>Regulatory Milestone</u>") by or on behalf of the Parties or their Affiliates or sublicensees with respect to the applicable Licensed Products described below in accordance with clauses 11.2.5 and 11.2.6.

Milestone event	Mile	estone Paymen	it (\$USD)
	[*] Product	[*] Product	[*] Product
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

Each Regulatory Milestone shall be [\*] by each [\*].

11.2.3 <u>Commercial Milestones</u>. In partial consideration for the rights and licenses granted by Genmab to Licensee under this Agreement, subject to clause 8.4 and clause 11.2.4, Licensee shall pay, or cause to be paid, to Genmab each of the following non-refundable, non-creditable payments upon the achievement of each of the following milestone events (each a "<u>Commercial Milestone</u>," and together with the

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Development Milestones and Regulatory Milestones, collectively, the "<u>Milestones</u>") by or on behalf of the Parties or their Affiliates or sublicensees on a Licensed Product-by-Licensed Product basis with respect to the applicable Licensed Products described below in accordance with clauses 11.2.5 and 11.2.6.

[*] Product	
Milestone event	Payment (\$USD)
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[*] Product and [*] Product		
Milestone event	Milestor	ne Payment (\$USD)
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

Each Commercial Milestone shall be payable [\*] by each of [\*].

- 11.2.4 <u>Licensed Products Containing [\*]</u>. Notwithstanding any provision in this Agreement to the contrary, Milestone payments payable to Genmab under this Agreement in respect of a [\*] shall solely be determined as follows:
  - (A) [\*]
  - (B) [\*]
  - (C) [\*]
  - (D) [\*]
  - [\*].

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

By way of example, [\*].

- 11.2.5 Notification and Payment of Milestone Payments. Licensee shall notify Genmab promptly in writing (and in any event within [\*]) of the achievement of any Development Milestone, Regulatory Milestone or Commercial Milestone in respect of First Commercial Sale of a Licensed Product. Licensee shall notify Genmab promptly in writing (and in any event within [\*] days following the end of the [\*]) upon becoming aware of the achievement of any aggregate Net Sales-based Commercial Milestone. Genmab shall then invoice Licensee for the payment of the associated Milestone which, subject to clause 8.4, shall be payable within the later of [\*]. Notwithstanding the foregoing, if Genmab becomes aware of the achievement of a Milestone prior to Licensee's notice, Genmab may issue an invoice at that time which is related to the genuine achievement of the relevant Milestone and subject to clause 8.4, the relevant Milestone payment set forth in clauses 11.2.1, 11.2.2 and 11.2.3 will be made within [\*] after the date of Genmab's invoice.
- 11.2.6 <u>Invoices</u>. Licensee shall pay, or cause to be paid, any amounts owed to Genmab, by wire transfer or electronic fund transfer to the credit of the bank account set out in Schedule 10. Invoices must be sent to Licensee at the address set out in clause 18.5 marked for the attention of AbbVie Biotechnology Ltd., with a copy to Licensee's co-chair of the JFS.
- 11.2.7 VAT. All sums payable under or pursuant to this Agreement are exclusive of VAT. Accordingly, where any taxable supply for VAT purposes is made under or in connection with this Agreement by one Party to the other, the recipient of that supply shall, in addition to any payment for that supply, pay to the supplier such VAT as is chargeable in respect of the supply at the same time as payment is due or in any other case when demanded by the supplier following receipt, where applicable, of an invoice in the appropriate form issued by the supplier in respect of those payments. If the VAT originally paid or otherwise borne by the recipient of any taxable supply are in whole or in part subsequently determined not to have been chargeable, all necessary steps will be taken by the supplier to receive a refund of the undue VAT from the applicable taxing authority and any amount of undue VAT repaid by such taxing authority to the supplier will be transferred to the recipient within forty-five (45) calendar days of receipt.

#### 11.3 Pre-Tax Profit or Loss

- 11.3.1 <u>Pre-Tax Profit or Loss</u>. Subject to clause 11.4, the Parties shall share in Pre-Tax Profit or Loss in the Territory for so long as the relevant Licensed Product is being sold in the Territory as follows:
  - (A) Genmab shall be entitled to and bear fifty percent (50%) of such Pre-Tax Profits or Loss; and
  - (B) Licensee shall be entitled to and bear fifty percent (50%) of such Pre-Tax Profits or Loss.

Procedures for: (i) quarterly reconciliation of such Pre-Tax Profit or Loss (calculated using the methodology in Schedule 10); and (ii) quarterly reporting of actual results and review and discussion of potential discrepancies, reasonable forecasting, and other finance and accounting matters, to the extent not set out in clauses 11.3.2, 11.3.3 or Schedule 10, will be established by the JFS (the "Net Sales Reconciliation Procedures"). Such procedures will provide the ability to comply with financial

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

reporting requirements of each Party. Subject to clause 11.4, such sharing of Pre-Tax Profit or Loss shall apply in respect of Territory B regardless of whether Genmab has exercised its rights under clause 7.3.2.

#### 11.3.2 Interim reports.

- (A) Within [\*] of the end of each [\*] and [\*] after First Commercial Sale of a Licensed Product, each Party shall provide the other Party and the JFS with a [\*]. Such [\*] shall also include a comparison of such estimated Net Sales to that Party's Commercialization Projection and the applicable Global Commercialization Budget for the same period, with accompanying commentary. The JFS shall promptly prepare consolidated [\*] and [\*] based on those reports provided by the Parties and shall provide such consolidated [\*] to the Chief Financial Officers of each Party. Such [\*] shall be provided as a courtesy estimate only and shall not be used as a basis of comparison against actual Pre-Tax Profit or Loss shares due or be considered binding in any way.
  - (B) Within [\*] of the end of each [\*], each Party shall provide the other Party and the JFS with its estimated Pre-Tax Profit or Loss for tfhat [\*] in respect of each Licensed Product using the calculation set out in Schedule 10 based only on its own estimated Net Sales and Other Income less its own Shared Costs.
- 11.3.3 [\*] Reconciliation and Payments. The Net Sales Reconciliation Procedures shall provide that within [\*] after the end of each [\*], each Party shall submit to the JFS and the JCC a report, in such reasonable detail and format as is established by the JFS, of all [\*] and other amounts necessary to calculate Pre-Tax Profit or Loss for the Territory. Following receipt of such report, each Party shall reasonably cooperate to provide additional information as necessary to permit calculation and reconciliation of Pre-Tax Profit or Loss for the Territory for the applicable [\*] by the JFS. The Net Sales Reconciliation Procedures shall provide for the JFS to develop a written report setting forth in reasonable detail the calculation of Pre-Tax Profit or Loss in the Territory for the applicable [\*] based on the principles set out in Schedule 10, amounts owed by Genmab to Licensee or by Licensee to Genmab, as the case may be. as necessary to accomplish the sharing of Pre-Tax Profit or Loss in the Territory for the applicable Calendar Quarter, and to prepare such report promptly following delivery of the reports from the Parties as described above in this clause and in a reasonable time (to be defined in the Net Sales Reconciliation Procedures) in advance of applicable payments to accomplish the sharing of Pre-Tax Profit or Loss in the Territory for the applicable [\*]. Payments to reconcile Pre-Tax Profit or Loss in the Territory, and Shared Costs, shall be paid by the applicable Party within [\*] after the end of each [\*]. Such payments shall be made to the bank accounts set out in Schedule 10.

# 11.4 Royalty Payable

11.4.1 Notwithstanding the terms of clause 11.3, the Parties acknowledge and agree that Net Sales of the [\*] Product in each country in Territory B (such product in such countries, a "Royalty Bearing Product") shall not be included in the Pre-Tax Profit or Loss described in clause 11.3 and, instead, subject to clause 11.4.5, Licensee shall pay Genmab a royalty on Net Sales of the Royalty Bearing Product sold by Licensee or its Affiliates in Territory B during each Calendar Year of the Royalty Term at the rates set forth below.

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Net Sales in Territory B of Royalty Bearing Product in a Calendar Year	Royalty Rate
For that portion of aggregate Net Sales of Royalty Bearing Products in Territory B during a Calendar Year [*]	22%
For that portion of aggregate Net Sales of Royalty Bearing Products in Territory B during a Calendar Year [*]	[*]
For that portion of aggregate Net Sales of Royalty Bearing Products in Territory B during a Calendar Year [*]	26%

For the avoidance of doubt, Net Sales of the [\*] Product in Territory A shall be subject to the Pre-Tax Profit or Loss share in clause 11.3 and shall not be subject to a royalty hereunder.

- 11.4.2 <u>Payment of Royalties</u>. Licensee shall pay all royalties earned pursuant to clause 11.4.1 in the preceding [\*] within [\*] after the end of that [\*]. All such payments shall be made in U.S. Dollars.
- 11.4.3 <u>Single Royalty</u>. Licensee and its Affiliates are not obliged to pay or cause to be paid to Genmab more than one royalty on any unit of Royalty Bearing Product in Territory B, irrespective of how many Genmab Patent Rights or Licensee Patent Rights may cover such Royalty Bearing Product in Territory B.
- 11.4.4 Report of Royalties. In addition to any other reporting to be provided to Genmab under this Agreement with respect to Licensee's Commercialization of Licensed Products, Licensee shall within [\*] after the end of each [\*] during the Royalty Term deliver to Genmab a written report showing its computation of royalties due under clause 11.4.1 on Net Sales of Royalty Bearing Products in Territory B during such [\*] ("Royalty Report"). Each such Royalty Report shall include: [\*]. Royalty Reports hereunder shall be deemed to be "Confidential Information" of both Parties and subject to the terms and conditions of clause 14.
- 11.4.5 <u>Royalty Reductions</u>. Subject to clause 11.4.6, if in any country in Territory B during the Royalty Term for the Royalty Bearing Product, a Third Party obtains Regulatory Approval for and commences sale of a Biosimilar with respect to the Royalty Bearing Product, and the aggregate Net Sales for Royalty Bearing Product decreases, on a country-by-country basis, by:
  - (A) [\*], in a given [\*] as compared to the average aggregate Net Sales for the Royalty Bearing Product in a [\*] in such country during the [\*] immediately preceding the [\*] in which such Biosimilar was launched (the [\*]), then the royalty rate set out in clause 11.4.1 shall be reduced by [\*] in respect of Net Sales in such affected country/ies where such Biosimilar is sold and such reduction shall continue for as long as [\*];
    - (B) [\*], in a given [\*] as compared to the [\*], then the royalty rate set out in clause 11.4.1 shall be reduced by [\*] in respect of Net Sales in such affected country/ies where such Biosimilar is sold and such reduction shall continue for as long as [\*];

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(C) [\*] in a given [\*] as compared to the [\*], then the royalty rate set out in clause 11.4.1 shall be reduced by [\*] in respect of Net Sales in such affected country/ies where such Biosimilar is sold and such reduction shall continue for as long as [\*],

provided that the same principles are applied in the calculation of such aggregate Net Sales as are usually and consistently applied by the Licensee during such Calendar Quarters. The royalty rate in other countries in Territory B where a Biosimilar is not on sale, or where a Biosimilar is on sale but aggregate Net Sales for the Royalty Bearing Product are not reduced by [\*] in a given [\*] as compared to the Pre-Biosimilar Launch Average in that country, shall remain unaffected.

11.4.6 <u>Cumulative Reductions</u>. Notwithstanding the reductions set forth in clause 11.4.5 and those shared Patent Costs permitted under clause 12.9 in respect of the Royalty Bearing Product in Territory B, in no event will the royalties payable to Genmab in a given [\*] be reduced by [\*] the aggregate amount that would otherwise have been due to Genmab pursuant to clause 11.4.1, provided, however, that Licensee may carry forward any such reductions permitted under clauses 11.4.5 or 12.9 that are incurred or accrued in a given [\*] but are not applied against the royalties due to Genmab in such [\*] as a result of the foregoing floor and apply such amounts against royalties due to Genmab in any subsequent [\*] until the amount of such reduction has been fully applied against royalties due to Genmab under this Agreement.

#### 11.5 **Audits**

Each Party and its Affiliates shall keep complete and accurate records of the items underlying Shared Costs, Other Income, Net Sales and the other elements required to prepare the reports or calculate payments required under this Agreement (including under clause 11.4.1) and the Reconciliation Procedures, and any other payments under this Agreement. Each Party will have the right annually at its own expense to have an independent, certified public accountant, selected by such Party and reasonably acceptable to the other Party, review any such records of the other Party and its Affiliates in the location(s) where such records are maintained by the other Party or its Affiliates upon [\*] notice and during regular business hours and under obligations of confidence, for the purpose of verifying the basis and accuracy of payments made under this Agreement and the Reconciliation Procedures, and any other payments due under this Agreement, within the prior [\*] period. If the review of such records reveals that the other Party has failed to accurately report information or make any payment (or portion thereof) required under this Agreement, then the other Party shall promptly pay to the auditing Party any underpaid amounts due under the Reconciliation Procedures, or otherwise due under this Agreement, together with interest calculated in the manner provided in clause 11.9. If any such discrepancies are an underpayment of amounts due under this Agreement greater than [\*] of the amounts actually due for any Calendar Year the other Party shall pay all reasonable external costs incurred in conducting such review. If such audit reveals that the other Party has made an overpayment, then the auditing Party shall promptly pay to the other Party any overpaid amounts due under the Reconciliation Procedures, or otherwise due under this Agreement, together with interest calculated in the manner provided in clause 11.9. [\*]. For clarity, however, if a discrepancy is identified by the accountant during the course of an audit and the Parties do not agree upon a resolution of such discrepancy, then the auditing Party's accountant may reinspect the books and records to the extent reasonably relevant to resolving such discrepancy. Parties will also cooperate with respect to documentation, assistance with information, and

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explanations that may reasonably be required for completion of the audit of the Party's financial statements and for compliance with the corporate governance code applicable to a Party.

#### 11.6 Tax matters

- 11.6.1 Each Party will make all payments to each other under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by Law in effect at the time of payment (with the determination of such required withholding made by the Party receiving the payment (the "Payee")) subject to the requirements set forth in clause 11.6.3.
- 11.6.2 Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by the Party making the payment (the "Payor") on behalf of the Payee to the appropriate Governmental Authority, and Payor will furnish Payee with proof of payment of such Tax. Any such Tax, to the extent withheld and paid to the appropriate Governmental Authority shall be treated for all purposes of this Agreement as having been paid to the Payee. Any such Tax required to be withheld will be an expense of and borne by Payee with the exception of any such Tax related to the upfront or Milestone payments due to Genmab pursuant to clauses 11.1 or 11.2 and arising by reason of Licensee's or its assignees' place of incorporation or tax residence. In the event that the upfront payment or Milestone payments due to Genmab pursuant to clauses 11.1 or 11.2 are subject to mandatory withholding or other similar Tax under applicable Laws by reason of Licensee's or its assignees' place of incorporation or tax residence, the relevant amounts otherwise due to Genmab pursuant to clauses 11.1 or 11.2, as applicable, shall be grossed up so that the amount received by Genmab after such withholding or similar Tax arising by reason of Licensee's or its assignees' place of incorporation or tax residence is deducted shall be the full amount Genmab would have received in the absence of such withholding or other similar Tax.
- 11.6.3 The Parties will cooperate with respect to all documentation required by any Governmental Authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes. If the withholding tax rate is reduced according to the provisions of an applicable double tax treaty or regulations applicable thereto, then no deduction or withholding shall be made (or such reduced amount shall be deducted or withheld), in each case as applicable, only if the Payor is timely furnished with necessary documents or certification by the Payee issued by the Governmental Authority certifying that the payment is exempt from Tax or subject to a reduced Tax rate or the Payee otherwise satisfies the requirements to obtain the treaty benefit in question. The Parties will also cooperate with respect to documentation that may reasonably be required for reporting any Tax position by the Parties under GAAP and IFRS.
- 11.6.4 Subject to clauses 11.6.2 and 15.13 and otherwise notwithstanding anything to the contrary set forth in this Agreement, if Payor had a duty to withhold Taxes in connection with any payment it made to Payee but Payor failed to withhold, and such Taxes were assessed against and paid by Payor, then Payee shall, at Payor's request and upon receipt of proof of Payor's payment of such Taxes, reimburse to Payor the amount equivalent to such Taxes paid by Payor. For the avoidance of doubt, Payee shall indemnify and hold harmless the Payor from and against not only any taxes, but also any related interest or penalties (other than penalties that result from a failure by Payor to follow the determination made by the Payee pursuant to

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- clause 11.6.1) that are imposed by the Governmental Authority against the Payor as withholding agent.
- 11.6.5 Prior to commencing Commercialization of any Licensed Product in any relevant jurisdiction within the Territory, the Parties hereby agree to cooperate in good faith to agree on tax reporting, including the preparation and filing of applicable tax returns. For the avoidance of doubt, Licensee agrees [\*]. The Parties shall use reasonable efforts to (i) [\*]

## 11.7 Currency exchange

- 11.7.1 <u>Currency of Payment</u>. All payments under this Agreement shall be paid in U.S. Dollars, by wire transfer to the account set out in Schedule 10 (which account the receiving Party may update from time to time in writing).
- 11.7.2 <u>Currency Conversion</u>. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are received or paid in a currency other than U.S. Dollars, then the Parties shall convert any such amount expressed in a foreign currency into U.S. Dollar equivalents using its, its Affiliate's or sublicensee's standard conversion methodology consistent with [\*].

## 11.8 Blocked payments

If, by reason of applicable Laws in any country, it becomes impossible or illegal for a Party or its Affiliate to transfer, or have transferred on its behalf, payments to the receiving Party, the paying Party shall promptly notify the receiving Party of the conditions preventing such transfer and such distribution fees or other payments shall be deposited in local currency in the relevant country to the credit of the receiving Party in a recognized banking institution designated by the receiving Party or, if none is designated by the receiving Party within a period of [\*], in a recognized banking institution selected by the paying Party or its Affiliate, as the case may be, and identified in a notice given to the receiving Party.

#### 11.9 Late payments

Subject to payments made under clauses 6.3 or 8.4, if a Party shall fail to make a payment pursuant to this Agreement when due, any such late payment shall bear interest, to the extent not prohibited by Law, at the annual rate of [\*] per annum above LIBOR or its successor rate, effective for the first date on which payment was delinquent and calculated on the number of calendar days such payment is overdue.

#### 11.10 Resolution of financial disputes

If there is a dispute, claim or controversy relating to any financial obligation by one Party to the other Party pursuant to this Agreement, the paying Party shall pay such undisputed amounts in accordance with the terms of this Agreement and provide such other Party with a written notice setting forth in reasonable detail the nature and factual basis for such good-faith dispute. Each Party agrees that it shall seek to resolve such dispute [\*] of the date such written notice is received. If no such resolution is reached by the Parties, the dispute shall first be referred to the JFS, then the JSC for resolution and if no such resolution is achieved, the matter shall be resolved through the procedures set out in clause 17.

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# 12. Intellectual Property Rights

#### 12.1 Interpretation

The Parties acknowledge and agree that the Genmab Intellectual Property includes Genmab Patent Rights and Genmab Know-How which Cover different aspects of the Licensed Products and which may be treated differently under this clause 12. In particular, for the purposes of this clause 12, the following terms shall have the following meanings:

- (A) "Genmab Product Patent Rights" shall mean those Genmab Patent Rights which Cover the [\*] and which do not constitute [\*].
- (B) "Genmab Technology Patent Rights" shall mean those Genmab Patent Rights which Cover the [\*], but excluding [\*].
- (C) "Genmab Right to Proceed or Combine Patent Rights" shall mean those Genmab Patent Rights that are [\*] owned or Controlled by Genmab, but excluding any [\*] that is owned by Genmab in connection with the performance of any [\*]
- (D) "Genmab Licensed Patent Rights" shall mean those Genmab Patent Rights which are licensed to Genmab from a Third Party (including those licensed under the Existing Third Party Agreements).
- (E) "Genmab Collaboration Technology Patent Rights" shall mean those Genmab Patent Rights that are part of the Genmab Collaboration Technology (excluding any Genmab Patent Rights in respect of the [\*].

The [\*] shall collectively be referred to as the "Genmab Reserved Patent Rights".

The list of Genmab Patent Rights in Schedule 6 shall identify which Patent Rights existing at the Effective Date are comprised within each of these categories of Genmab Patent Rights set out above.

# 12.2 Ownership of Collaboration Technology

- 12.2.1 Each Party shall promptly inform the other Party in writing of any Collaboration Technology conceived or reduced to practice, discovered, developed or otherwise made by it or its Affiliates, alone or jointly with others, in the performance of this Agreement.
- 12.2.2 Genmab shall exclusively own:
  - (A) [\*]
    - (B) [\*]

(collectively, "[\*]"). Licensee hereby assigns (and shall procure that its Affiliates, and any of its or their employees, agents and consultants assign) (by way of present assignment of future rights) to Genmab (or its designated Affiliate) absolutely, with full title guarantee, all rights, title and interests Licensee or its Affiliates (or any of their employees, agents or consultants) has or may come to have in and to any and all [\*] for no further consideration. To the extent such assignment is not effective under this

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

Agreement or otherwise by operation of law, Licensee shall hold such rights, title and interests on trust for Genmab and immediately assign the same by written instrument to Genmab (or its designated Affiliate) on request, for no further charge.

- 12.2.3 Licensee shall exclusively own all [\*] ("Licensee Collaboration Technology").
- 12.2.4 [\*].
- 12.2.5 To the extent applicable and permitted by Law Licensee hereby waives, and agrees to procure that its and its Affiliates' personnel waive, in favor of Genmab, all moral rights Licensee or its or its Affiliates' personnel has or may have under the Copyright Designs and Patents Act 1988 of the United Kingdom or other similar Laws in the [\*], now or at any time in the future.

## 12.3 Prosecution and maintenance of Patent Rights globally

- 12.3.1 Genmab Product Patent Rights and Genmab Collaboration Technology Patent Rights. [\*] shall have the first right to prepare, file, prosecute, validate, maintain, defend and extend (except as set forth in clause 12.7.1) the Genmab Product Patent Rights and Genmab Collaboration Technology Patent Rights on a global basis. [\*] shall promptly provide [\*] with copies of all material correspondence to or from the U.S. Patent and Trademark Office ("USPTO"), European Patent Office ("EPO") and equivalent patent offices in foreign jurisdictions, relating to the Genmab Product Patent Rights or Genmab Collaboration Technology Patent Rights. [\*] shall take into account (acting in good faith) and consider [\*] reasonable interests (regarding the Licensed Products in the Field) and requests regarding the preparation, filing, prosecution, validation, maintenance, defense and extension of Genmab Product Patent Rights or Genmab Collaboration Technology Patent Rights under this clause. If [\*] does not wish to file or continue prosecution, validation, maintenance or defense of one or more Genmab Product Patent Rights or Genmab Collaboration Technology Patent Rights in any country or region pursuant to this clause 12.3.1, it shall notify [\*] of the same and [\*] may (at its election) take over such preparation, filing, prosecution, validation, maintenance, defense or extension of the Genmab Product Patent Rights or Genmab Collaboration Technology Patent Rights in the name of [\*] in such country or region, and [\*] shall reasonably cooperate with [\*] in such country or region after such taking over such activities. For the avoidance of doubt, all Out-of-Pocket Costs relating to the preparation, filing, prosecution, validation, maintenance, defense and extension of Genmab Product Patent Rights or Genmab Collaboration Technology Patent Rights shall constitute [\*].
- 12.3.2 <u>Genmab Reserved Patent Rights</u>. [\*] shall have the exclusive right to prepare, file, prosecute, validate, maintain, defend and extend the Genmab Reserved Patent Rights on a global basis. [\*] shall provide [\*] with regular updates relating to the status of the Genmab Reserved Patent Rights. [\*] shall be solely responsible for all costs relating to the preparation, filing, prosecution, validation, maintenance, defense and extension of Genmab Reserved Patent Rights.
- 12.3.3 [<u>\*</u>].[\*].
- 12.3.4 <u>Licensee Patent Rights</u>. Subject to clause 12.3.5, [\*] shall have the exclusive right to prepare, file, prosecute, validate, maintain, defend and extend the Licensee Patent Rights on a global basis. [\*] shall provide [\*] with regular updates and status relating to such Licensee Patent Rights. [\*] shall be solely responsible for all costs relating to

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the preparation, filing, prosecution, validation, maintenance, defense and extension of such Licensee Patent Rights.

12.3.5 <u>Licensee Collaboration Technology.</u> [\*] shall have the first right to prepare, file, prosecute, validate, maintain, defend and extend (except as set forth in clause 12.7) those Licensee Patent Rights that are part of the Licensee Collaboration Technology ("Licensee Collaboration Technology Patent Rights") on a global basis in close consultation and coordination with [\*]. [\*] shall promptly provide [\*] with draft applications and copies of all material correspondence to or from the USPTO, EPO and equivalent patent offices in foreign jurisdictions, relating to the Licensee Collaboration Technology Patent Rights. [\*] shall closely coordinate and consult with [\*] and take into account (acting in good faith) and consider [\*] reasonable interests (regarding the Licensed Products in the Field) and requests regarding the preparation, filing, prosecution, validation, maintenance and defense of Licensee Collaboration Technology Patent Rights under this clause. If [\*] does not wish to file an application or does not wish to continue prosecution, validation, maintenance or defense of one or more Licensee Collaboration Technology Patent Rights under this clause, it shall notify [\*] of the same and [\*] may (at its election) take over such preparation, filing, prosecution, validation, maintenance or defense of the Licensee Collaboration Technology Patent Rights in the name of [\*], and [\*] shall reasonably cooperate with [\*] in such country or region after such taking over such activities. For the avoidance of doubt, all Out-of-Pocket Costs relating to the preparation, filing, prosecution, validation, maintenance and defense of Licensee Collaboration Technology Patent Rights shall constitute [\*].

# 12.4 Third Party infringement

- 12.4.1 Each Party shall promptly notify the other Party of any apparent, threatened or actual infringement by a Third Party with respect to a product similar to a Licensed Product of any Genmab Patent Rights [\*] or Licensee Patent Rights of which it becomes aware.
- 12.4.2 <u>Enforcement of Genmab Product Patent Rights, Genmab Collaboration Technology Patent Rights and Licensee Collaboration Technology Patent Rights.</u>
  - (A) Enforcing Party. If either Party reasonably determines that a Third Party is marketing or plans to market a product similar to a Licensed Product in the Territory which would or is reasonably likely to infringe [\*], then such Party shall promptly notify the other Party of such determination, [\*]. The Party that is the lead party instituting and controlling such infringement Action pursuant to this clause 12.4.2 or 12.4.5 (as applicable) shall be referred to as the "Enforcing Party", and if the Parties jointly control such infringement Action, then both Parties shall be considered the Enforcing Party for such suit or action. [\*].
  - (B) <u>Joint Proceedings</u>. If the Parties jointly institute such infringement Action during such joint Action, all decisions relating to such Action shall be made jointly by the Parties, and the Parties agree to work in good faith to come to consensus agreements, and to compromise wherever reasonably possible; and in the event that the Parties are still unable to resolve an issue arising from and during such infringement Action, [\*]
  - (C) <u>Participation</u>. The Enforcing Party (if only Genmab or Licensee is the Enforcing Party) shall have the right to institute and control such infringement

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Action in the name of Genmab or of Licensee, or in the names of both of them as required by applicable Law. If the Enforcing Party institutes an infringement Action in accordance with clause 12.4.2(A)(ii), the non-Enforcing Party shall have the right, in the non-Enforcing Party's sole discretion to join or otherwise participate in such legal action (including actively participating in material enforcement strategy decisions or other material decisions in respect of such proceeding). The Out-of-Pocket Costs of such participation shall [\*].

- (D) <u>Step-In Rights</u>. If the Enforcing Party (if only Genmab or Licensee is the Enforcing Party) decides not to institute or control such infringement Action, or has not taken reasonable steps to institute or prepare to institute such infringement Action in the Territory within a period of [\*], then the Enforcing Party shall timely notify the non-Enforcing Party and the non-Enforcing Party may, in its sole discretion, institute and control such infringement Action, and in such event, such Party shall become the Enforcing Party hereunder.
- 12.4.3 <u>Enforcement of Genmab Reserved Patent Rights</u>. [\*] shall have the exclusive right to institute an infringement Action under the Genmab Reserved Patent Rights [\*]. [\*] shall have the right to institute such infringement Action in the name of Genmab or of Licensee, or in the names of both of them as required by applicable Law. [\*].
- 12.4.4 [\*]. [\*]
- Biosimilar filings. In the event of a BLA filed by a Third Party under Section 351(k) of the United States 12.4.5 Public Health Service Act (PHSA) for a Biosimilar (a "Biosimilar Filing"), the Parties shall discuss and jointly agree, in accordance with clause 12.4.2(A) whether: (i) [\*], in close consultation with the other Party, to institute and manage an infringement Action, or (ii) [\*] shall [\*] institute and manage an infringement Action, under the [\*] in respect of such Biosimilar Filing. If it is not legally possible for [\*] institute such an infringement Action, the Parties shall agree which Party shall be the Party on record for such infringement Action but such infringement Action shall be conducted as determined jointly by the Parties. [\*] shall have the right to institute such infringement Action in the name of Genmab or of Licensee or in the names of both of them as required by applicable Law. The non-Enforcing Party shall have a right, [\*]. If Genmab or Licensee as the Enforcing Party decides not to institute or control an infringement Action against said Third Party, or has not taken reasonable steps to institute or prepare to institute such infringement Action [\*] from receiving the information provided by the Third Party pursuant to 351(I)(1)(B) of the PHSA or a notice from the Third Party regarding such Biosimilar Filing, then the other Party shall be free to bring an infringement Action against said Third Party in respect of such Biosimilar Filing with respect to [\*]. All other provisions of clause 12.4.2 shall be applicable to any patent enforcement action brought against a Third Party in response to said Biosimilar Filing. For the avoidance of doubt, the Out-of-Pocket Costs of a non-Enforcing Party participating in such Action shall constitute [\*] save that if the non-Enforcing Party [\*].
- 12.4.6 Enforcement of Licensee Patent Rights. Subject to clauses 12.4.2 and 12.4.5, [\*] shall have the exclusive right to institute infringement Action under the Licensee Patent Rights [\*]. [\*] shall have the right to institute such Action in the name of Licensee or of Genmab, or in the names of both of them as required by applicable Law. [\*].

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- 12.4.7 Cooperation. In any suit or enforcement action brought under the [\*] as described in clauses 12.4.2 12.4.6, each Party shall, and shall cause its Affiliates to, fully cooperate with the litigating Party (if only Genmab or Licensee is the litigating Party), in good faith, and agree to be and shall join as a party to such suit at the litigating Party's request, if necessary, provided that the litigating Party shall continue to control such suit. The litigating Party shall provide the other Party with reasonable prior notice and opportunity to review and comment, and shall consider in good faith all reasonable comments from such other Party, on any official papers, statements or proposed arguments asserted or to be asserted in litigation related to the enforcement of any [\*] (or defense of same in response to any Third Party counter-claim) in connection with the Licensed Products. The litigating Party enforcing [\*]. The litigating Party enforcing [\*]. All information exchanged between the Parties in connection with any Action as described in clauses 12.4.2 12.4.6 will be deemed to be Confidential Information of the disclosing Party. [\*]. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege, including privilege under the common interest doctrine and similar or related doctrines. [\*].
- 12.4.8 <u>Conduct of certain actions; costs.</u> Except as provided in subclause (iii) of clause 12.4.2(A), the litigating Party shall have the [\*].
- 12.4.9 Recoveries. With respect to any Action initiated pursuant to this clause 12.4, any recovery obtained as a result of any such Action, by settlement or otherwise, shall be applied in the following order of priority:
  - (A) [\*]
  - (B) [\*]

# 12.5 Patent invalidity claim

## 12.5.1 Right to respond.

- (A) If, during the Term, a Third Party initiates an Action asserting that Genmab Patent Rights Covering the Licensed Product(s) in the Field are invalid or otherwise unenforceable (a "Genmab Invalidity Claim"), [\*] shall control the response to such Genmab Invalidity Claim, provided that if such Genmab Invalidity Claim is a counterclaim, declaratory judgment claim adjudicated in the same proceeding as any infringement Action, or otherwise part of the same litigation involving an infringement Action against such Third Party, then the Party that has the right to control the infringement Action pursuant to clause 12.4 shall control the response to such Genmab Invalidity Claim. [\*].
- (B) If, during the Term, a Third Party initiates an Action asserting that Licensee Patent Rights Covering the Licensed Product(s) in the Field are invalid or otherwise unenforceable (a "<u>Licensee Invalidity Claim</u>"), [\*] shall control the response to such Licensee Invalidity Claim, provided that if such Licensee Invalidity Claim is a counterclaim, declaratory judgment claim adjudicated in the same proceeding as any infringement Action, or otherwise part of the same litigation involving an infringement Action against such Third Party, then [\*].

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(C) For the avoidance of doubt, save as set out therein, clauses 12.5.1 and 12.5.2 shall apply to those Actions brought before a court of competent jurisdiction as a primary claim and shall not apply to any [\*].

# 12.5.2 Conduct of Certain Actions; Costs.

- (A) The non-responding Party under clause 12.5.1 shall cooperate with the responding Party in the preparation and formulation of a response to a Genmab Invalidity Claim or Licensee Invalidity Claim (as applicable), and in taking other steps reasonably necessary to respond, to such Genmab Invalidity Claim or Licensee Invalidity Claim at the responding Party's request.
- (B) The responding Party shall have the [\*] for the response to such Genmab Invalidity Claim or Licensee Invalidity Claim (as applicable).
- (C) If required under applicable Law in order for the responding Party to maintain a suit in response to such Genmab Invalidity Claim or Licensee Invalidity Claim, the other Party shall join as a party to the proceedings at the responding Party's request. The non-responding Party under clause 12.5.1 shall offer reasonable assistance to the responding Party in connection therewith at the responding Party's request. [\*].
- (D) [\*] shall not settle or compromise any [\*] Invalidity Claim in respect of any Genmab Product Patent Rights or Genmab Collaboration Technology Patent Rights [\*].
- (E) [\*] shall not settle or compromise any [\*] Invalidity Claim in a manner that [\*].
- (F) [\*].

# 12.6 Claimed infringement

- (A) Each of the Parties shall promptly notify the other if: (1) it reasonably suspects that the [\*] may infringe a Third Party's Intellectual Property Rights; or (2) any Third Party initiates any Action alleging patent infringement by Licensee or Genmab or any of their respective Affiliates with respect to the [\*] (any such Action referred to herein as an "Infringement Claim").
- (B) In the case of any Infringement Claim, [\*] control the defense and response to any Infringement Claim, save that if and to the extent the Infringement Claim solely relates to the use of the [\*] shall have the exclusive right to control the defense and response to any such Infringement Claim.
- (C) With respect to any Infringement Claim, [\*].

# 12.7 Patent term extensions

12.7.1 <u>Genmab Product Patent Rights and Genmab Collaboration Technology Patent Rights and Licensee Collaboration Technology Patent Rights.</u> With respect to a Licensed Product, [\*], determine which Genmab Product Patent Rights and Genmab Collaboration Technology Patent Rights, if any, shall be extended pursuant to U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary

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- 12.7.2 <u>Genmab Reserved Patent Rights and Genmab Licensed Patent Rights</u>. With respect to a Licensed Product, and subject to clause 12.7.1, [\*] shall have the sole discretion, in due consultation with [\*], to determine which Genmab Reserved Patent Rights, if any, shall be extended pursuant to U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the EU and other similar measures in any other country. [\*].
- 12.7.3 <u>Licensee Patent Rights</u>. With respect to a Licensed Product, and subject to clause 12.7.1, [\*] shall have the sole discretion, in due consultation with [\*], to determine which Licensee Patent Rights, if any, shall be extended pursuant to U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the EU and other similar measures in any other country. [\*]

#### 12.8 Trademarks

- 12.8.1 <u>Retained rights in corporate marks and logos</u>. Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names and logos.
- Licensed Products Trademark. The Parties shall aim to use one global Licensed Product Trademark in the Territory in connection with the Commercialization of each of the Licensed Products in the Field unless agreed otherwise by the JCC. Such Licensed Product Trademarks shall be included in the Global Brand Plans. The Licensed Product Trademarks shall be initially filed and prosecuted by [\*] and upon grant of such registered Licensed Product Trademarks, as well as the International Nonproprietary Name or other name or identifier for the Licensed Compound, [\*]. The Licensed Product Trademarks, and the International Nonproprietary Name or other name or identifier for the Licensed Compound, shall be maintained, enforced and defended in the same manner as for the Genmab Collaboration Technology Patent Rights as described in clauses 12.3 to 12.7 above mutatis mutandis. [\*]. If Licensed Product Trademarks are used, the Parties shall use the trademark registration symbol ® or TM, as appropriate, in connection with the Licensed Product Trademarks. [\*].

## 12.9 New Third Party Patent Rights

- 12.9.1 Notification. If, during the Term, a Party determines, in its reasonable judgment, that it is [\*] to obtain rights under any New Third Party Patent Rights in order to Develop, Manufacture or Commercialize a Licensed Product in the Field in accordance with this Agreement, then said Party shall promptly notify the other Party, and the Parties shall discuss such matter, including: [\*] if such a license or acquisition would be so desirable, then which Party shall obtain such a license (with any such license being sublicensable and assignable to the other Party and its Affiliates and sublicensable to Subcontractors and sublicensees) or make such acquisition. Upon the request of either Party, the Parties shall seek the advice of [\*].
- 12.9.2 <u>Allocation of Patent Costs.</u> If the Parties agree to either take invalidity or revocation Action or procure a license of (or acquire) such New Third Party Patent Rights, then, in each case, [\*]:

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- (A) if such New Third Party Patent Rights are only necessary to practice the [\*] in the context of the Licensed Product(s), then such amounts will be borne solely by [\*]. [\*]; and
- (B) if such New Third Party Patent Rights are practiced by the Parties to further Develop, Manufacture or Commercialize the Licensed Products and are also practiced by or on behalf of the licensing or acquiring Party (or Parties) to develop, manufacture or commercialize other products, then only: [\*].
- 12.9.3 <u>Dispute Resolution</u>. If the Parties do not agree with respect to the matters described in clauses 12.9.1 or 12.9.2, then such matter shall be referred to the [\*] for resolution. If the [\*] cannot agree whether to [\*]. [\*].

# 13. **Data**

- 13.1 The Parties agree that where legally permissible they shall each have the right to access and use all Data as a data controller of such Data (as that term is defined under the General Data Protection Regulations 2016/679), including to the extent possible and legally permissible outside the scope of this Agreement [\*]. Any publication of Data shall be made in accordance with clause 14.3.
- 13.2 Promptly following the Effective Date, the Parties shall enter into a data protection agreement containing appropriate provisions in respect of the sharing of such Data in accordance with applicable data protection Laws (the "<u>Data Protection Agreement</u>") Without limiting the foregoing, the Parties shall:
  - (A) [\*];
  - (B) [\*];
  - (C) [\*];
  - (D) [\*];
  - (E) [\*];
  - (F) [\*];
  - (G) [\*];
  - (H) [\*]
  - (I) [\*].
- 13.3 For all Personal Data collected, Processed, hosted, or transmitted in performance by either Party of this Agreement, including in connection with the conduct of the activities under any GDP, GCP or GMAP (and all plans incorporated into any of them), the Parties shall comply with all applicable Data Security and Privacy Laws and the terms of the Data Protection Agreement.
- 13.4 In the event of any conflict or inconsistency between the provisions of this clause 13 and the provisions of the Data Protection Agreement, the provisions of the Data Protection Agreement shall take precedence to the extent of the conflict or inconsistency.

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#### 14. Confidentiality and publicity

#### 14.1 Confidential Information

- 14.1.1 During the Term and for a period of [\*] after any termination or expiration of this Agreement, each Party agrees to, and shall cause its Affiliates to:
  - (A) keep in confidence and not to disclose to any Affiliates or Third Party; and
  - (B) not use for any purpose (except in order to have the benefit of its rights, or to perform its obligations under, this Agreement),

any Confidential Information of the other Party.

Notwithstanding the foregoing, a Party may disclose such other Party's Confidential Information to: (1) its Affiliates, Subcontractors, sublicensees and its and their employees, agents and consultants that need to know such Confidential Information in connection with the performance of such Party's obligations under this Agreement; (2) Third Parties who are parties to an Existing Third Party Agreement to the extent necessary to comply with the terms of such agreement as such terms exist as of the Effective Date; and (3) advisors (including financial advisors, attorneys and accountants), business consultants, or actual or potential acquisition partners, collaboration partners, licensees, sublicensees or private investors, in each case as may be necessary in connection with the Development, Commercialization, Manufacture or other exploitation of the Licensed Products, or otherwise in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement, and in each case ((1)-(3)) such disclosure shall only be of that Confidential Information which is strictly necessary to be disclosed for the performance of the relevant purpose by such persons and provided always that such persons are under an obligation of confidentiality and non-use no less strict than the obligations in this clause 14.1. Each Party shall be liable for any unauthorized use or disclosure of such Confidential Information by any Person to whom Confidential Information is disclosed pursuant to this clause 14.1.1(B). As used herein, "Confidential Information" shall mean all confidential or proprietary information of the disclosing Party or its Affiliates given or disclosed to (or otherwise learned by via the disclosing Party and its Affiliates) the other Party or its Affiliate, whether disclosed in tangible or intangible form, which is marked or stated to be "Confidential" or "Proprietary" (or words of similar import) or which would reasonably by the nature of the subject matter or the manner of its disclosure be considered as being confidential or proprietary, including: (i) information relating to the business, affairs, customers, clients, suppliers, plans, intentions, or market opportunities of the disclosing Party or of the disclosing Party's group; (ii) the terms of this Agreement; and (iii) information relating to any materials or Know-How generated in connection with the performance of this Agreement. Data shall constitute the Confidential Information of both Parties. For purposes of this Agreement: (i) all Confidential Information that was disclosed by Genmab or its Affiliate to Licensee under the Prior CDA shall be deemed Confidential Information of Genmab, and all Confidential Information that was disclosed by Licensee to Genmab or its Affiliate under the Prior CDA shall be deemed Confidential Information of Licensee; (ii) any confidential or proprietary information of either Party directed to the Licensed Products shall be deemed the Confidential Information of both Parties, save that any confidential or proprietary information specifically directed to the [\*]; and (iii) [\*].

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<sup>[\*] =</sup> Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

- 14.1.2 The restrictions in clause 14.1 shall not apply to any Confidential Information that:
  - (A) was known by the receiving Party or its Affiliate prior to disclosure by the disclosing Party or its Affiliates hereunder or under the Prior CDA (as evidenced by the receiving Party's or such Affiliates' written records or other competent evidence);
  - (B) is or becomes part of the public domain through no fault of the receiving Party or its Affiliates in violation of this Agreement;
  - (C) is disclosed to the receiving Party or its Affiliates by a Third Party (excluding Affiliates) having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party or an Affiliate thereof; or
  - (D) is independently developed by personnel of the receiving Party or its Affiliate without reliance on the Confidential Information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence).
- 14.1.3 Notwithstanding the foregoing, each Party may use and disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary in connection with:
  - (A) filing or prosecuting patent applications claiming the Licensed Products or any aspect of the Development, Manufacture or Commercialization of the Licensed Products (such filing and prosecution to be conducted subject to applicable procedures set out in this Agreement);
  - (B) conducting pre-clinical studies or Clinical Studies according to the Global Development Plans;
  - (C) seeking Regulatory Approval of the Licensed Products and in Regulatory Filings or other communications or submissions to Regulatory Authorities, or submitting information to tax or other Governmental Authorities:
  - (D) prosecuting, enforcing or defending litigation; or
  - (E) complying with applicable Laws or court orders, including securities Laws and the rules of any securities exchange or market on which a Party's (or its Affiliates') securities are listed or traded.

If either Party or any of its Affiliates is required to disclose Confidential Information of the other Party as described above, to the extent permitted by Law, such Party shall: (a) provide prior notice of such intended disclosure to such other Party if possible under the circumstances; (b) disclose only such Confidential Information of such other Party as is required to be disclosed; and (c) allow the other Party to intervene to protect the confidentiality of the information and oppose such disclosure and, to the extent allowable by Law, to seek limitations on the portion of the Confidential Information that is required to be disclosed.

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# 14.2 Publicity

- 14.2.1 Upon the execution of this Agreement, the Parties shall issue mutually agreed press releases regarding the subject matter of this Agreement, including a description of the aggregate financial terms and value of the Agreement, in the forms set out in Schedule 11. The Parties shall coordinate on the time and date on which such press releases are issued.
- 14.2.2 <u>Further Publicity.</u> The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Products in the Field and other activities in connection with this Agreement. Except for the initial press releases described in clause 14.2.1, neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's (in-house or outside) counsel, required by applicable Law or the rules of a stock exchange on which the securities of the disclosing Party (or its Affiliates) are listed. In the event a Party is, in the opinion of its (in-house or outside) counsel, required by applicable Law or the rules of a stock exchange on which its (or its Affiliates') securities are listed to make such a public disclosure, such Party shall whenever reasonably possible submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [\*] prior to the anticipated date of disclosure [\*], in which case, the disclosing Party shall provide as much notice as reasonably possible) so as to provide a reasonable opportunity to comment thereon.
- 14.2.3 Notwithstanding the foregoing, a Party may issue such press release or public announcement without such prior review by the other Party if: (i) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by the issuing Party; and (ii) such press release or public announcement does not materially differ from the previously issued press release or other publicly available information.

#### 14.3 Publications

14.3.1 The JDC shall develop a global publication strategy for the publication of any Development and Commercialization activities related to each of the Licensed Products in the Field (collectively the "Global Publication Strategies") that is consistent with the GDPs and the GCPs, for approval by the JSC. The initial Global Publication Strategies shall be included in the GDPs at an appropriate time as mutually agreed by the JDC and shall include the core content of any scientific publications and presentations relating to the Licensed Products globally. The JDC may from time to time develop and submit to the JSC for approval, other proposed substantive changes and updates to the Global Publication Strategies. For the avoidance of doubt such Global Publication Strategies would apply to the content of any International Scientific Research publications and Health Economic and Outcome Research publications.

The JSC shall review such proposed substantive changes and updates presented by the JDC and may approve such proposed substantive changes and updates or any other proposed substantive changes and updates that the JSC shall consider from time to time in its discretion and, upon such approval by the JSC, the Global Publication Strategies shall be amended accordingly.

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Notwithstanding the foregoing (or clause 14.3.2), the Global Publication Strategies shall not be construed to limit a Party's rights to make disclosures pursuant to clause 14.2.

14.3.2 <u>Approval of Publications</u>. The Parties shall ensure that any publications which it wishes to publish comply with the applicable Global Publication Strategies, the Parties' respective compliance policies and applicable Law. The Parties shall agree [\*].

# 15. Representations, warranties and liability

## 15.1 Representations of Authority

Genmab and Licensee each represents and warrants to the other Party that, as of the Effective Date, it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement and that it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement.

## 15.2 Consents

Genmab and Licensee each represents and warrants to the other Party that, except for any [\*], and all necessary consents, approvals and authorizations of all Governmental Authorities required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained by the Effective Date.

#### 15.3 No conflict

Genmab and Licensee each represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder (as contemplated as of the Effective Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate any requirement of Laws existing as of the Effective Date and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date. Each Party shall, and shall cause its Affiliates to, comply with all Laws applicable to the Development, Manufacture and Commercialization of the Licensed Products, including applicable Drug Regulation Laws, Clinical Trial Laws and Health Care Laws.

## 15.4 Enforceability

Genmab and Licensee each represents and warrants to the other Party that, as of the Effective Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

# 15.5 Genmab Intellectual Property

Genmab represents and warrants that:

(A) [\*] Genmab or its Affiliates [\*] owns the Genmab Intellectual Property which is in existence at the Effective Date;

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- (B) as of the Effective Date, Genmab does not own any Patent Rights or Know-How that would be included in the Genmab Intellectual Property [\*];
- (C) as at the Effective Date, [\*] for the Development, Manufacture and Commercialization of the Licensed Products;
- (D) it has the right to grant the licenses in clause 4.1;
- (E) [\*], the Genmab Licensed Patent Rights [\*].
- (F) as at the Effective Date, there are [\*] relating to the Genmab Intellectual Property; and
- (G) as at the Effective Date: (i) in respect of Genmab Intellectual Property which is owned by it or its Affiliates, [\*].

The foregoing representations and warranties shall apply only in respect of those [\*], [\*] and [\*] clinical candidates existing at the Effective Date and listed in part (A) of their respective definitions.

## 15.6 Prior Development

Genmab represents and warrants to Licensee that:

- (A) [\*], Genmab and its Affiliates have conducted, and their respective contractors and consultants have conducted, all Development of the Licensed Compounds and the Licensed Products (including any pre-clinical and Clinical Studies with respect thereto) in accordance with good laboratory and clinical practice and applicable Law; and
- (B) Genmab and its Affiliates have employed persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the pre-clinical studies and Clinical Studies with respect to the Licensed Compounds and Licensed Products.

# 15.7 Confidentiality

Genmab represents and warrants to Licensee that Genmab and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Genmab Know-How that constitutes trade secrets under applicable Law (including requiring all employees, consultants, and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants, and independent contractors to maintain the confidentiality of such Genmab Know-How, for a customary period of time in respect of the nature and scope of activities conducted by such employee, consultant or independent contractor) and, to Genmab's Knowledge, the Genmab Know-How has not been used, disclosed to or discovered by any Third Party except pursuant to a confidentiality agreement and to Genmab's Knowledge there has not been a breach by any party to such confidentiality agreements.

# 15.8 Existing Third Party Agreements

Genmab represents and warrants to Licensee that:

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- (A) as of the Effective Date, there are no Third Party agreements [\*] necessary to perform the Development, Manufacture or Commercialization of the Licensed Products as envisaged under this Agreement which Genmab [\*];
- (B) as of the Effective Date, [\*], no Third Party has any rights, title or interests in or to, or any license under, any of the [\*] that would conflict with the rights and licenses granted to Licensee hereunder;
- (C) except as referenced in Schedule 5, in [\*] there are no material limitations, conditions or obligations applicable to Licensee as a sublicensee of the Intellectual Property Rights licensed to Genmab under the Existing Third Party Agreements;
- (D) Genmab has provided Licensee with a [\*] copy of each of the Existing Third Party Agreements pursuant to which either (i) Genmab has been licensed rights to any material Intellectual Property Rights included in the Genmab Intellectual Property or (ii) material obligations are required to be imposed on Licensee as a sublicensee under such Existing Third Party Agreements. To [\*], each Existing Third Party Agreement is [\*] has been received or given under any Existing Third Party Agreement. To [\*], there is no [\*] by Genmab or its Affiliates that would provide a right to terminate any such Existing Third Party Agreement; and
- (E) any such redacted portions of those Existing Third Party Agreements [\*] to enable Licensee to comply with its obligations to Genmab under this Agreement.

The foregoing representations and warranties shall apply only in respect of those [\*], [\*] and [\*] clinical candidates existing at the Effective Date and listed in part (A) of their respective definitions.

# 15.9 Regulatory Filings

Genmab represents and warrants to Licensee that Genmab and its Affiliates have generated, prepared, maintained, and retained all Regulatory Filings that are required to be maintained or retained pursuant to and in accordance with good laboratory and clinical practice and applicable Law in order to perform those Development activities which have been performed by Genmab in respect of the Licensed Products prior to the Effective Date.

#### 15.10 Genmab Affiliates

Genmab represents, warrants and covenants to Licensee that at the Effective Date:

- (A) [\*] are Affiliates of Genmab;
- (B) All Intellectual Property Rights Controlled by Genmab that relate to the [\*] clinical candidate existing at the Effective Date (and listed in part (A) of that defined term of [\*]) are owned by [\*] or [\*] referred to in Schedule 5; and
- (C) Genmab has obtained all necessary rights from all of its Affiliates to grant the licenses and rights to Licensee contemplated under this Agreement.

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## 15.11 Licensee Intellectual Property

Licensee represents and warrants that:

- (A) as at the Effective Date, [\*]; and
- (B) it has the right to grant the licenses in clause 4.2.

#### 15.12 Competing Products

Licensee represents and warrants that, as of the Effective Date, neither it nor any of its Affiliates is developing, manufacturing or commercializing any Competing Product, nor is it or any of its Affiliates planning or preparing to do so after the Effective Date.

15.13 [\*]

Licensee represents and warrants that, as of the Effective Date, [\*].

# 15.14 No debarment

Each Party represents and warrants that, as of the Effective Date, neither it nor any of its Affiliates has been debarred or is subject to debarment under applicable Law, and neither Party nor any of its Affiliates will use in any capacity, in connection with the Development, Manufacture or Commercialization of the Licensed Products in the Field, any Person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or any other applicable Law, or who is the subject of a conviction described in such section. Each Party agrees to inform the other Party in writing immediately if it or any Person who is performing services for it hereunder is debarred or is the subject of a conviction described in Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or any other applicable Law, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party's knowledge, is threatened, relating to the debarment or conviction of such Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the Development, Manufacture or Commercialization of the Licensed Products.

#### 15.15 Additional Genmab Covenants

- 15.15.1 Genmab will not assign, transfer, convey or grant any license or other rights to its rights, title and interests in or to the Genmab Intellectual Property (or agree to do any of the foregoing) in any way that would materially conflict with any of the rights or licenses granted to Licensee hereunder.
- 15.15.2 Genmab will not, and will cause its Affiliates not to, incur or permit to exist, with respect to any Genmab Intellectual Property, any lien, encumbrance, charge, security interest, mortgage, liability, or other restriction (including in connection with any indebtedness) if and to the extent that the same would materially conflict with any of the rights or licenses granted to Licensee hereunder.
- 15.15.3 Genmab will not terminate any Existing Third Party Agreement pursuant to which Genmab has been licensed rights to any material intellectual property included in the Genmab Intellectual Property if and to the extent that such termination would materially conflict with or materially reduce any of the rights or licenses granted to Licensee hereunder. Genmab shall not breach any such Existing Third Party

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Agreement in a manner that would give rise to the right of any Third Party to terminate such Existing Third Party Agreement. Genmab will promptly notify Licensee if it receives any notice from a Third Party, or if it issues any notice to such Third Party, alleging a breach under such Existing Third Party Agreement giving rise to a right of termination. Genmab will not amend, modify or terminate any Existing Third Party Agreement in a manner that would materially adversely affect Licensee's rights hereunder without first obtaining Licensee's written consent.

15.15.4 Genmab will not take, and will cause its Affiliates not to take, any action (or fail to take any action) that would cause Genmab to cease to Control any Genmab Intellectual Property which is owned by Genmab B.V. or Genmab Holding B.V. during the Term.

#### 15.16 No warranties

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE LICENSED PRODUCTS, GENMAB INTELLECTUAL PROPERTY OR LICENSEE INTELLECTUAL PROPERTY. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF THE LICENSED PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR NET SALES LEVEL WITH RESPECT TO THE LICENSED PRODUCTS WILL BE ACHIEVED.

#### 15.17 Compliance with Laws

- 15.17.1 Each Party shall comply fully during the Term with, and shall cause its personnel and Affiliates, sublicensees, Subcontractors and other Third Party service providers that provide services to it or its Affiliates in support of its obligations under this Agreement, to comply with all applicable anti-corruption Laws in connection with the performance of this Agreement, and shall not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any act in furtherance of, or receive or offer to receive, any payment or transfer of anything of value, for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage with the purpose or effect of public or commercial bribery.
- 15.17.2 Each Party shall implement and maintain in force for the Term adequate internal anti-corruption policies and risk-based management systems with respect to providing relevant information, education and training to, and monitoring compliance of, its personnel with all applicable anti-corruption Laws, including without limitation appropriate whistleblowing arrangements and internal anti-corruption compliance auditing.
- 15.17.3 Each Party shall comply fully during the Term with, and shall cause its personnel and Affiliates, sublicensees, Subcontractors and other Third Party service providers that provide services to it or its Affiliates in support of its obligations under this Agreement, to comply in all material respects with all applicable Laws (including all applicable Competition Laws) in connection with the performance of this Agreement.

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#### 15.18 Insurance

- (A) Beginning at the time any Licensed Products are being distributed, sold or Commercialized, each Party will secure and maintain in full force and effect adequate insurance coverage against its liabilities under this Agreement including commercial general liability and product liability insurance in an amount not less than [\*] per claim and annual aggregate. Such insurance shall be maintained beyond the expiration or termination of this Agreement for a period of [\*] thereafter.
- (B) Prior to the initiation of any Clinical Study, the Party responsible for the applicable Clinical Study shall be responsible for and secure and maintain in full force and effect clinical trial insurance in compliance with applicable Law and in accordance with industry standards in those territories where Clinical Studies are conducted. Upon written request, each Party shall provide the other with a certificate of insurance evidencing the required coverage. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance shall not relieve that Party of its obligations set out in this Agreement.
- (C) Notwithstanding the foregoing, Licensee may self-insure, in whole or in part, the insurance requirements described above.
- (D) [\*].

#### 15.19 Indemnities

- 15.19.1 <u>General indemnity by Genmab</u>. Genmab shall indemnify and hold harmless Licensee, its Affiliates and their respective directors, officers, employees and agents (collectively, the "<u>Licensee Indemnified Parties</u>") from, against and in respect of any and all damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, Taxes, expenses or amounts paid in settlement (in each case, including reasonable attorneys' and experts fees and expenses) (collectively, "<u>Losses</u>"), incurred or suffered by the Licensee Indemnified Parties or any of them, resulting from an Action brought by a Third Party or Governmental Authority as a result of, arising out of or relating to: [\*] Agreement by any of the Licensee Indemnified Parties or any material breach of, or material inaccuracy in, any representation or warranty made by Licensee in this Agreement.
- 15.19.2 <u>General indemnity by Licensee</u>. Licensee shall indemnify and hold harmless Genmab, its Affiliates and their respective directors, officers, employees and agents (collectively, the "<u>Genmab Indemnified Parties</u>"), from, against and in respect of any and all Losses incurred or suffered by the Genmab Indemnified Parties or any of them resulting from an Action brought by a Third Party or Governmental Authority as a result of, arising out of or relating to: [\*]
- 15.19.3 Notice. A person entitled to indemnification under clause 15.19.1 or 15.19.2 (an "Indemnified Party") shall give prompt written notification to the person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any Action, for which indemnification may be sought (each, a "Claim") or, if earlier, upon the assertion of any such Claim by a Third Party; provided, however, failure by an Indemnified Party to give notice of a Claim as provided in this clause 15.19.3 shall not relieve the Indemnifying Party of its indemnification obligation under this

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- Agreement, except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice.
- 15.19.4 <u>Defense</u>. Within [\*] after delivery of a notice of any Claim in accordance with clause 15.19.3, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense.
- 15.19.5 <u>Cooperation</u>. The Party controlling the defense of any Claim shall keep the other Party advised of the status of such Claim and the defense thereof and shall reasonably consider recommendations made by the other Party with respect thereto. The other Party shall cooperate fully with the Party controlling such defense and its Affiliates and agents in the defense of the Claim (all Out-of-Pocket Costs of such cooperation to be borne by the Indemnifying Party).
- 15.19.6 <u>Settlement</u>. The Indemnified Party shall not agree to any settlement of such Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party or adversely affects the Indemnified Party's Intellectual Property Rights without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld.

# 15.20 Conduct of Licensed Products Liability Claims.

- 15.20.1 <u>Licensed Products Liability Costs</u>. Except with respect to such portion (if any) of Licensed Products Liability Costs that are Losses entitled to indemnification under clause 15.19.1(i)-(iii) or 15.19.2(i)-(iii), all other [\*].
- 15.20.2 Each of the Parties shall promptly notify the other if any Third Party asserts or files any [\*] ("Third Party Licensed Products Liability Action") against such Party. In the event of a Third Party Licensed Products Liability Action against such a single Party, the Party named in such Third Party Licensed Products Liability Action shall have the right to control the defense of the action, but shall notify and keep the unnamed Party apprised in writing of such action and shall consider and take into account the unnamed Party's reasonable interests and requests and suggestions regarding the defense of such action. The unnamed Party shall have the right, in the unnamed Party's sole discretion, to join or otherwise participate in such legal action and the costs of such participation shall constitute Patent Costs, save that if the unnamed Party wishes to be represented by its own legal counsel (who is reasonably acceptable to the named Party) such expenses shall be borne solely by such unnamed Party and shall not constitute Shared Licensed Products Liability Costs. In the event of a Third Party Licensed Products Liability Action and if the Parties are unable to agree, such Third Party Licensed Products Liability Action shall be controlled by the Parties jointly.
- 15.20.3 The non-controlling Party of a Third Party Licensed Products Liability Action shall reasonably cooperate with the controlling Party in the preparation and formulation of a defense to such Third Party Licensed Products Liability Action, and in taking other steps reasonably necessary to respond to such Third Party Licensed Products

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Liability Action. The controlling Party shall have the sole and exclusive right to select its counsel for the defense to such Third Party Licensed Products Liability Action. If required under applicable Law in order for the controlling Party to maintain an Action in response to such Third Party Licensed Products Liability Action, the non-controlling Party shall join as a party to the Action. For the avoidance of doubt, all Out-of-Pocket Costs incurred in connection with any Third Party Licensed Products Liability Action shall constitute Shared Licensed Products Liability Costs unless such Licensed Products Liability Costs are entitled to indemnification under clause 15.19.1 or 15.19.2 or are incurred by the unnamed Party in respect of its own legal counsel. The controlling Party shall not settle or compromise any Third Party Licensed Products Liability Action without the consent of the other Party, which consent shall not be unreasonably withheld.

#### 16. <u>Term and termination</u>

# 16.1 [Intentionally left blank]

#### 16.2 **Term**

Unless terminated earlier in accordance with this clause 16, this Agreement shall remain in force for the period commencing on the Effective Date and ending upon the date on which neither Party is Developing or Commercializing the Licensed Products in the Territory (the "Term").

16.3 **Termination by Licensee**. Licensee may terminate this Agreement on a Licensed Product-by-Licensed Product or Region-by-Region basis, or in its entirety, at any time after the Effective Date upon [\*] prior written notice to Genmab.

#### 16.4 Termination for material breach

Upon any material breach of this Agreement by a Party with respect to a given Licensed Product in a given Region or Regions (the "Breaching Party"), where such material breach cannot adequately be cured through monetary damages as a remedy, the other Party (the "Non-Breaching Party") may elect to terminate this Agreement with respect to such Licensed Product in such Region(s) (or in its entirety [\*]) by providing [\*] written notice to the Breaching Party in the case of a breach of a payment obligation and [\*] written notice to the Breaching Party in the case of any other material breach, which notice shall, in each case (i) expressly reference this clause 16.4, (ii) reasonably describe the alleged material breach which is the basis of such termination, and (iii) clearly state the Non-Breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. For the avoidance of doubt, if such material breach is with respect to all Regions for a given Licensed Product, then the Agreement shall terminate for that Licensed Product in respect of the entire Territory (subject to the Non-Breaching Party's right to terminate the Agreement in its entirety as described above).

The termination shall become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period, and such termination shall only apply to those Licensed Product(s) and Region(s) to which such material breach relates unless terminated in its entirety. Notwithstanding the foregoing:

(A) in the event of a good faith dispute with respect to the existence of a material breach, such cure periods described above shall be tolled until such time as the dispute is resolved pursuant to clause 17; and

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(B) if such material breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period shall be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses best efforts to cure such breach in accordance with such written plan during such cure period, provided that no such extension shall exceed a further [\*] without the consent of the Non-Breaching Party.

## 16.5 Termination upon bankruptcy

16.5.1 Either Party may, in addition to any other remedies available to it by Law or in equity, terminate this Agreement in its entirety, by notice to the other Party in the event: (i) the other Party shall have become bankrupt or shall have made an assignment for the benefit of its creditors; (ii) there shall have been appointed a trustee or receiver for the other Party for all or a substantial part of its property; or (iii) any case or proceeding shall have been commenced or other action taken by or against the other Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect, and any such event shall have continued for sixty (60) calendar days undismissed, unbonded and undischarged.

# 16.5.2 Section 365(n) of the Bankruptcy Code.

All rights and licenses granted under or pursuant to any clause of this Agreement, including clause 4, are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "Bankruptcy Code")). Genmab and Licensee hereby acknowledge, on behalf of themselves and their respective Affiliates, that (i) Data, (ii) laboratory samples, (iii) product samples and inventory, (iv) formulas, (v) laboratory notes and notebooks, (vi) Regulatory Filings and Regulatory Approvals, and (viii) marketing, advertising and promotional materials, constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code. Each of Genmab and Licensee agree not to, and to cause their respective Affiliates not to, interfere with the other Party's or its Affiliate's exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agree to use Commercially Reasonable Efforts to assist the other Party or its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary for the other Party or its Affiliates to exercise such rights and licenses in accordance with this Agreement.

## 16.6 Termination for Force Majeure

Either Party shall have the right to terminate this Agreement in accordance with clause 18.2.

#### 16.7 Consequences of expiry

Expiry. In the event of expiration of this Agreement this clause 16.7 shall apply.

(A) <u>Accrued Obligations</u>. Expiration of this Agreement shall not release either Party from any obligation or liability which, at the time of such expiration, has

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already accrued to the other Party or which is attributable to a period prior to such expiration.

- (B) <u>Licenses</u>. All licenses granted under clause 4 shall immediately terminate and, save as permitted under clause 16.8:
  - (a) [\*]; and
  - (b) Genmab shall not have any license from Licensee, either explicit or implicit, to use any of the Licensee Intellectual Property and the Licensed Product Trademarks.

Genmab shall have all available legal remedies against [\*], and Licensee shall have all available legal remedies against Genmab [\*]. Subject to clause 14 the Parties acknowledge and agree that expiration of this Agreement shall not in any way restrict their use and exploitation of any Joint Collaboration Technology pursuant to clause 12.2.4.

- (C) <u>Assignment</u>. [\*] shall immediately execute a confirmatory assignment of the Genmab Collaboration Technology in accordance with clause 12.2.2.
- (D) Sublicenses. All sublicenses granted under clause 4.3 shall immediately terminate and the sublicensing Party shall procure that such sublicensees cease all use of the Genmab Intellectual Property, Licensee Intellectual Property and Licensed Product Trademarks pursuant to this Agreement.
- (E) <u>Governance</u>. The Committees and Subteams and JPTs shall be disbanded and cease to take any actions.
- (F) Return of Materials. Within [\*] after expiry, each Party shall return or destroy, and cause its Affiliates, sublicensees and Subcontractors to return or destroy, all tangible items (and irretrievably erase all intangible items) solely comprising, bearing or containing any Confidential Information of the other Party that are in its or its Affiliates', sublicensees' or Subcontractors' possession or control, and provide written certification of such destruction (if applicable), provided that such Party (and its Affiliates, sublicensees and Subcontractors) may retain one copy of such Confidential Information of the other Party for its legal archives. Each Party hereby agrees that, with respect to items and materials that contain both Confidential Information of the other Party and other information (including any joint Confidential Information of both Parties), such first Party and its Affiliates shall not use or disclose the Confidential Information of the other Party contained in such items and materials following expiry and the terms of clause 14 shall continue in respect of the same.
- (G) Post-expiry Shared Licensed Product Liability Costs. If a Party or any of its Affiliates incurs any Shared Licensed Products Liability Costs after the Term and after the final reconciliation of Shared Costs under clause 8 in accordance with the Shared Costs Reconciliation Procedures, which Shared Licensed Products Liability Costs are attributable to sales or other activities under this Agreement prior to expiration of the Term or to Launched Licensed Products sold pursuant to clause 16.8.2 or 16.8.3, each Party shall be responsible for half of such Shared Licensed Products Liability Costs. Each Party will promptly pay the other Party its share of any such Shared Licensed

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Products Liability Costs after receipt of detailed supporting documentation evidencing such Shared Licensed Products Liability Costs.

#### 16.8 Consequences of termination

- 16.8.1 General. Upon termination of this Agreement:
  - (A) all Licensed Products with respect to which this Agreement is terminated (in the form such Licensed Products exist as of the effective date of termination) shall become "Terminated Products";
    - (B) any Region with respect to which this Agreement is terminated pursuant to clause 16.3 or clause 16.4 will be referred to herein as a "<u>Terminated Region</u>";
    - (C) all Regions in the Territory shall be considered Terminated Regions if the Agreement is terminated in its entirety pursuant to clauses 16.4, 16.5 or 16.6.

For the avoidance of doubt, if this Agreement is terminated in its entirety, then all Licensed Products will become Terminated Products, and all Regions in the Territory will become Terminated Regions.

- 16.8.2 <u>Genmab Termination for Cause, Insolvency or Force Majeure</u>. If Genmab terminates this Agreement with respect to a Terminated Product or Terminated Region or in its entirety pursuant to clauses 16.4, 16.5 or 16.6 or if Licensee terminates with respect to a Terminated Product or Region pursuant to clause 16.3, Genmab shall have the [\*]:
  - (A) Governance during Wind-Down. Beginning on the effective date of termination [\*].
  - (B) Regulatory Filings and Data. [\*].
  - (C) On-Going Trials. [\*].
  - (D) <u>Commercialization Wind-Down</u>. [\*].
  - (E) <u>Transition; Manufacturing; Inventory</u>. [\*].
  - (F) <u>Intellectual Property Rights</u>.
    - (a) The licenses granted by Genmab under clause 4.1 with respect to such [\*].
    - (b) [\*].
    - (G) Marks and Domains. [\*].
    - (H) Additional terms. [\*].
- 16.8.3 <u>Licensee Termination for Cause, Insolvency or Force Majeure</u>. If Licensee terminates this Agreement with respect to a Terminated Product or Terminated Region(s) or in its entirety pursuant to clauses 16.4, 16.5 or 16.6, Licensee shall have the exclusive right to Develop, Manufacture and Commercialize the Terminated Product(s) in the

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Terminated Region(s) and the following provisions of this clause 16.8.3 shall apply solely with respect to such Terminated Product(s) in such Terminated Region(s):

- (A) Governance during Wind-Down. [\*]
- (B) Regulatory Filings and Data. [\*]
- (C) On-Going Trials. [\*]
- (D) <u>Commercialization Wind-Down</u>. [\*]
- (E) <u>Transition; Manufacturing; Inventory</u>. [\*]

[\*]

- (F) Intellectual Property Rights.
  - (a) [\*] [\*]
  - (b) [\*]
- (G) Marks and Domains. [\*]
- (H) Additional terms. [\*]
- 16.8.4 Termination on a Region-by-Region Basis. Without limiting clauses 16.8.2(A) -16.8.2(H) and 16.8.3(A) -16.8.3(H), if a Party terminates this Agreement with respect to a Region pursuant to clauses 16.3 or 16.4, then as soon as reasonably practicable following: (i) Licensee's delivery of its termination notice to Genmab under clause 16.3; or (ii) the Non-Breaching Party's delivery of its termination notice to the Breaching Party under clause 16.4, (and in any event within [\*] of such termination notices) the Parties shall discuss in good faith and agree upon a transition plan to effect an orderly and timely transition to the continuing Party of the Development, Manufacturing and Commercialization activities for the Licensed Product(s) in respect of the Terminated Region(s). Such transition plan may include amendments to, or obligations in addition to, those obligations set out in clauses [\*] [\*] or [\*] [\*] to the extent reasonably necessary to effect such [\*]. By way of example, such changes may include [\*]. Such [\*] shall provide for orderly and timely coordinated efforts by the Parties to [\*] and such other elements as may be agreed by the Parties.
- 16.8.5 <u>Survival</u>. In the event of any termination or expiration of this Agreement, any provision of this agreement that expressly or by implication is intended to come into or continue in force on or after termination or expiry of this Agreement, including clauses 4.3.5, 4.5, 11.5, 11.7, 11.8, 11.9, 11.10, 12.2, 14.1, 14.2, 15 (solely for the purposes of bringing or maintaining claims that arose prior to the termination or expiration of this Agreement), 16.7, 16.8, 17, 18.1, 18.3, 18.5, 18.9, 18.12, 18.14 and 18.15 (and any other clauses or defined terms which are referred to in such clauses or necessary to give them effect), shall remain in full force and effect. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement shall survive to the extent required.

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## 17. Dispute resolution

## 17.1 Referral to [\*]

In the event of: any controversy, dispute or claim arising out of, or in connection with, or in relation to the formation, interpretation, performance, or alleged breach of this Agreement, including any claim of inducement by fraud or otherwise or any Governance Dispute that, in each case, the Parties have not resolved (each a "Dispute"), either Party may provide written notice to the other Party to (A) in the case of matters not already before the JSC, refer such Dispute in writing to the JSC for resolution; or (B) in the case of matters that are already before the JSC that have not been resolved, request resolution of such Dispute by the JSC. If the JSC does not resolve such Dispute within [\*] after the receipt of such written notice (unless a longer period is agreed to by the Parties), then either Party may refer the Dispute in writing to the Parties' [\*] for resolution. If the [\*] fail to resolve such Dispute within [\*] from the date on which the Dispute was referred to the [\*] (unless a longer period is agreed to by the Parties), then the provisions set out in clauses 17.2 and 17.3 shall apply; provided however that:

- (A) with respect to the contents of any Territory Commercialization Plan (including the applicable Territory Commercialization Budget) for the [\*], Licensee's [\*] shall have the deciding vote (which shall not be subject to challenge, review or arbitration) with respect thereto, provided that each such Territory Commercialization Plan for the [\*] shall be consistent with the Global Commercialization Plan for the [\*] Product;
- (B) with respect to whether to permit sublicensing in [\*], the sublicensing Party's [\*] shall have the deciding vote (which shall not be subject to challenge, review or arbitration) with respect thereto;
- (C) with respect to whether to permit Subcontracting in [\*] the Subcontracting Party's [\*] shall have the deciding vote (which shall not be subject to challenge, review or arbitration) with respect thereto;
- (D) any disagreement between the Parties regarding the exercise of the Right to Proceed Mechanism or Right to Combine Mechanism shall be finally decided in accordance with clauses 6.3.1 or 6.4 (as applicable) (which decision shall not be subject to challenge, review or arbitration);
- (E) any disagreement of the JRS and JSC as to whether to submit any Regulatory Filing to a Regulatory Authority pursuant to clause 6.6.3 shall be finally decided by: (i) [\*] [\*] and (ii) by [\*] [\*] (in each case such decision shall not be subject to challenge, review or arbitration);
- (F) any disagreement between the Parties regarding whether to [\*] shall be finally decided by [\*];
- (G) any disagreement between Genmab and Licensee as the [\*] shall be finally decided in accordance with clause 12.4.2(B) (which decision shall not be subject to challenge, review or arbitration);
- (H) any disagreement between Genmab and Licensee as to whether to take Action against, or license or acquire, any New Third Party Patent Rights shall

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be finally decided in accordance with clause 12.9.3 (which decision shall not be subject to challenge, review or arbitration); and

(I) all other matters that are expressly identified in this Agreement as being not subject to challenge, review or arbitration shall not be subject to the terms of clauses 17.2 and 17.3,

and provided further with respect to subclauses 17.1(A)-(I) that neither Licensee nor Genmab may use any of their respective deciding votes described in clauses (A) and (B) in a manner that would (i) impose on the non-deciding Party any new obligation to perform Development, Manufacturing, Commercialization or other activities as to which such deciding Party has not agreed in writing to reimburse the non-deciding Party or to treat as Shared Costs hereunder, (ii) reduce or abridge the non-deciding Party's rights under this Agreement, or (iii) amend, modify or waive compliance with this Agreement, which may only be amended or modified as provided in clause 18.12 or compliance with which may only be waived as provided in clause 18.4.

#### 17.2 Arbitration

- 17.2.1 Subject to clause 17.3, if any Dispute (excluding those described in subclauses 17.1(A)-(C)) has not been resolved pursuant to clause 17.1 above, then the Parties shall settle the Dispute through binding arbitration conducted in accordance with the then-current [\*] except where those rules conflict with these provisions, in which case these provisions shall prevail. The arbitration will be held in [\*]. The Parties agree that they will not challenge the jurisdiction or authority of the arbitration panel to decide the dispute or the arbitrability or admissibility of the relevant Dispute.
- 17.2.2 The arbitration panel shall consist of [\*] arbitrators each of whom is a lawyer with at [\*] experience with a law firm or corporate law department of [\*] lawyers or who was a judge of a court of general jurisdiction, and has experience in the pharmaceutical or biotechnology industry, provided, that the Parties shall discuss and determine whether each such arbitrator shall be required to have additional or other experience or qualifications relevant to the subject matter of a Governance Dispute; provided further that if the Parties shall have failed to agree on any such additional or other experience or qualifications, the arbitrators shall in any event meet the initial requirements of this clause 17.2.2. [\*] However, in the event the aggregate damages sought by the claimant are stated to be less than [\*], and the aggregate damages sought by in any counter-claim are stated to be less than [\*]and neither side seeks equitable relief, then a single arbitrator shall be chosen mutually by the Parties, having the same qualifications and experience specified above. Each arbitrator shall be neutral, independent, disinterested and impartial and shall abide by the International Bar Association's Guidelines on Conflicts of Interest in International Arbitration.
- 17.2.3 The Parties agree to cooperate: (i) to select the arbitrator(s) within [\*] of initiation of the arbitration, (ii) to meet with the arbitrator(s) within [\*] of selection, and (iii) to agree at that meeting or before upon the scope of and procedures for pre-hearing disclosure and as to the conduct of the hearing which will result in the hearing being concluded within no more than [\*] after selection of the arbitrator(s) and in the award being rendered within [\*] of the conclusion of the hearings or of any post-hearing briefing, which briefing will be completed by both sides within [\*] after the conclusion of the hearings.

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- 17.2.4 In the event that either Party fails to select an arbitrator within [\*] of the initiation of the arbitration, or in the event that the Parties cannot agree upon selection of the tribunal president, the [\*] will select such arbitrator, provided that such arbitrator shall have the experience requirements set out above.
- 17.2.5 In the event the Parties cannot agree upon procedures for disclosure and conduct of the hearing according to the schedule set out in clause 17.2.3 then the arbitrator(s) shall set dates for the hearing, any post-hearing briefing, and the issuance of the award in accordance with the schedule set out in clause 17.2.3. The arbitrator(s) may provide for disclosure consistent with those time limits and giving recognition to the shared understanding of the Parties that they contemplate reasonable disclosure, including, as may be justified in the circumstances, document disclosure and depositions, but that such disclosure be limited so that the schedule set out in clause 17.2.3 shall be met. In no event will the arbitrator(s), absent agreement of the Parties or a showing of good cause, allow more than a total of [\*] for the hearing or permit either side to obtain more than a total of [\*] of deposition testimony from all fact and expert witnesses, or serve more than twenty [\*] for documents, including subparts. Multiple hearing days will be scheduled consecutively to the greatest extent possible.
- 17.2.6 The arbitrator(s) must render their award by application of the substantive law of the state of New York and are not free to apply "amiable compositeur" or "natural justice and equity"; provided that for any Governance Dispute submitted to the arbitrator(s) that fell within the decision-making responsibilities of any Committee or Subteam in accordance with the terms of this Agreement, the arbitrator(s) must render their decision applying the substantive law of the state of [\*] and based on the principles of maximizing the commercial potential and value of the Licensed Product(s) that pertain to such Governance Dispute, which shall be considered a "term of the contract" for purposes of [\*]. The arbitrator(s) shall render a written opinion setting forth findings of fact and conclusions with the reasons therefore stated. A transcript of the evidence adduced at the hearing shall be made and shall, upon request, be made available to either Party. The arbitrator(s) shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of such ruling on evidence. The Tribunal shall also have the authority to award fees and costs (including reasonable attorney's fees) to the prevailing party. To the extent possible, the arbitration hearings and award will be maintained in confidence.
- 17.2.7 The Parties consent to the jurisdiction of the [\*] for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. If such court for any reason lacks jurisdiction, the Parties consent to the jurisdiction of the [\*].

## 17.3 Intellectual Property Rights

- 17.3.1 In respect of any Dispute relating to the determination of scope, ownership, inventorship, validity or enforceability of any Intellectual Property Rights hereunder, the Parties consent to the exclusive jurisdiction of the courts of the country the Laws of which cause that Intellectual Property Right to come into being and where such courts have jurisdiction the Dispute shall be determined according to the Laws of that country.
- 17.3.2 No Party shall be precluded from taking any preliminary or interim steps, such as applying to court for injunctive relief, as may be necessary to protect that Party's position regarding its Intellectual Property Rights or the confidentiality of its

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Confidential Information, whilst any discussions or arbitration are being conducted pursuant to this clause 17.

#### 18. Miscellaneous

## 18.1 Accounting Procedures

Each Party shall calculate all amounts hereunder and perform other accounting procedures required hereunder and applicable to it in accordance with the conventions, rules and procedures promulgated by GAAP, consistently applied.

# 18.2 Force Majeure

If the performance of this Agreement or of any obligation hereunder (other than an obligation to make payments hereunder) is prevented, restricted or interfered with by reason of Force Majeure, the obligated Party shall be excused from such performance to the extent of such prevention, restriction or interference; provided however, the obligated Party shall promptly advise the other Party of the existence of such prevention, restriction or interference, shall use its reasonable efforts to avoid or remove such causes of non-performance and shall continue performance hereunder whenever such causes are removed. If any Force Majeure delays or prevents the performance of the obligations of either Party for a continuous period in excess of [\*], the Party not so affected shall then be entitled to give notice to the affected Party to terminate, unless [\*] in which case the Party not so affected shall only be entitled to give notice to the affected Party to terminate if: (A) the affected Party's performance of its obligations has been delayed or prevented due to such Force Majeure for more than [\*]; and (B) such continuing Force Majeure does not apply more generally to the biopharmaceutical industry or other Party such that the affected Party has been [\*]. By way of example, if an affected Party is unable to perform a Clinical Study due to Force Majeure directly relating to [\*] for more than [\*] whereas other biopharmaceutical companies are generally able to perform Clinical Studies notwithstanding the [\*] then such affected Party shall be considered to be disproportionately affected and the other Party may terminate the Agreement after such [\*] period. Such a termination notice shall be irrevocable, except with the written consent of both Parties.

#### 18.3 Further Assurance

Either Party shall (and shall procure that its Affiliates shall and shall use reasonable efforts to procure that any necessary other Third Party shall) at any time, including after the expiration or termination of this Agreement, upon the request of the other, and at the other's cost, do and execute all such acts, deeds, documents and things as may reasonably be required for the purpose of giving full effect to this Agreement (including to perfect and complete the grant of, or, in accordance with the terms of this Agreement, otherwise protect, the rights and licenses hereby conferred upon the other), subject to any express restrictions in this Agreement on the extent of either Party's obligations under this Agreement.

# 18.4 Waiver

Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No failure to exercise nor any delay in exercising by any Party to this Agreement of any right, power, privilege or remedy under this Agreement shall impair

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or operate as a waiver thereof in whole or in part, and no single or partial exercise of any right, power, privilege or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right, power, privilege or remedy. Subject to the specific exclusions and limitations and express provisions to the contrary set out in this Agreement, all rights, powers, privileges and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers, privileges or remedies provided by law or otherwise.

#### 18.5 Notices

All notices required or permitted under this Agreement shall, except where otherwise specifically provided, be in writing and be sent by air courier or by electronic mail (with a confirmation copy by air courier) properly addressed to the respective Parties as follows:

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If to [*]

[*]

or

the address of [*]

or

the address of [*]

If to [*]:

AbbVie Inc.

[*]

with a copy to (which shall not constitute notice):

Ropes & Gray LLP

[*]

[*]
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or to such other addresses or addressees as the Parties hereto may designate in writing for such purposes during the Term.

Notices shall be deemed to have been made: (i) if by electronic mail, when the e-mail leaves the e-mail gateway of the sender where it leaves such gateway on or before 17:00 hours on any Business Day, or at 08:00 hours on the next Business Day after it leaves such gateway if it leaves such gateway after 17:00 hours (and the onus shall be on the sender to prove the time that the e-mail left its gateway), and (ii) if by air courier, two (2) Business Days after delivery to the courier. All times shall be deemed to refer to the time in the recipient's local time.

## 18.6 Independent Contractors

No agency, partnership or joint venture is hereby established; each Party shall act hereunder as an independent contractor. Neither Genmab nor Licensee shall enter

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into, or incur, or hold itself out to Third Parties as having authority to enter into, or incur, on behalf of the other Party any contractual obligations, expenses or liabilities whatsoever.

#### 18.7 Assignment

This Agreement shall be binding upon the Parties and their respective permitted successors and assigns. Neither Party may assign [\*]; or (ii) to [\*].

#### 18.8 Change of Control

- 18.8.1 If a Party undergoes a Change of Control during the Term, the following shall apply (as applicable):
  - (A) all [\*];
  - (B) all [\*]; and
  - (C) [\*].
- 18.8.2 If Genmab is the Party that undergoes a Change of Control during the Term, the following shall apply as of and following the effective date of such Change of Control:
  - (A) [\*]
  - (B) [\*],

unless the Acquirer of Genmab has a company value based on market capitalization of [\*] in which case the terms of this clause 18.8.2 shall not apply. [\*]

- 18.8.3 If a Party or any of its Affiliates, either as a result of: (i) an acquisition by such Party or its Affiliates of a Third Party or any of its business or assets; or (ii) a Change of Control of such Party, obtains ownership, license or other rights to any Competing Product (or, as a result of such acquisition or Change of Control, has as an Affiliate that has an ownership, license or other rights, to any Competing Product) and the Licensed Product with which it competes is still being actively Developed, Manufactured or Commercialized under the Agreement, then such Party (the "Competing Party") shall promptly:
  - (A) [\*]; and
  - (B) notify the other Party in writing that it is:
    - (a) [\*] or
    - (b) [\*].

# 18.9 No Benefit to Third Parties

Except as provided herein, the provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other persons.

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#### 18.10 Use of Name

Except as provided herein, neither Party may use in any manner the other Party's or its Affiliates' name, trade name or corporate logo, or any contraction, abbreviation or adaptation thereof, without the express written consent of the other Party.

#### 18.11 Severability

When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be illegal, void, invalid or unenforceable under the Laws of any jurisdiction, such provision will be ineffective only to the extent of such prohibition or invalidity, and the legality, validity and enforceability of the remainder of this Agreement in that jurisdiction shall not be affected (unless the provision in question is of such essential importance to this Agreement that it may be reasonably presumed that the Parties would not have entered into this Agreement without the invalid or unenforceable provision), and the legality, validity and enforceability of the whole of this Agreement in any other jurisdiction shall not be affected. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic, legal and commercial effect is as consistent as possible with the invalid or unenforceable provision.

#### 18.12 Entire Agreement; Amendments

This Agreement, together with the Schedules, the Prior CDA, Supply Agreement, Data Protection Agreement, Pharmacovigilance Agreement (and any other documents referred to herein) constitute the entire agreement between the Parties relating to the subject matter hereof and supersedes all prior and contemporaneous negotiations, agreements, representations, understandings and commitments with respect thereto whether written or oral. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Each Party acknowledges that it has not been induced to enter into this Agreement by any representation or warranty other than those contained in this Agreement and, having negotiated and freely entered into this Agreement, agrees that it shall have no remedy in respect of any other such representation or warranty provided that nothing herein shall exclude or limit liability for fraudulent misrepresentation. No release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

#### 18.13 Variation

No terms or provisions of this Agreement shall be varied, extended or modified by any prior or subsequent statement, conduct or act of either of the Parties, except by a written instrument specifically referring to this Agreement and signed by both Parties.

#### 18.14 Governing Law

Subject to clause 17 and to any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction, this Agreement and any non-contractual obligations arising from or connected with it shall be governed by [\*] and this Agreement shall be construed in accordance with [\*].

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# 18.15 Counterparts

This Agreement may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Agreement.

# [Signature page follows.]

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IN WITNESS WHEREOF, each Party has caused to representative, in duplicate on the dates written herein by	his Agreement to be duly executed by its authorized below.
Signed for and on behalf of	
Genmab A/S	
by Jan van de Winkel	
and	CEO & President
Deirdre P. Connelly	Chairman of the Board of Directors
Signed for and on behalf of	
AbbVie Biotechnology Ltd.	Director
by Esteban Plata Gonzalez	
1	.00
[*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.	

# Genmab A/S

# Subsidiaries of the Registrant

Name	Jurisdiction of Incorporation
Genmab B.V.	The Netherlands
Genmab US, Inc.	Delaware, United States

#### CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

#### I, Jan G. van de Winkel, certify that:

- 1. I have reviewed this annual report on Form 20-F of Genmab A/S;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of Genmab A/S as of, and for, the periods presented in this report;
- 4. The other certifying officer of Genmab A/S and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for Genmab A/S and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to Genmab A/S, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of disclosure controls and procedures of Genmab A/S and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in internal control over financial reporting of Genmab A/S that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect internal control over financial reporting of Genmab A/S.
- 5. The other certifying officer of Genmab A/S and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the auditors of Genmab A/S and the audit committee of the board of directors of Genmab A/S (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the ability of Genmab A/S to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the internal control over financial reporting of Genmab A/S.

Date: March 29, 2021

/s/ Jan G. van de Winkel

AMERICAS/2017215015.2

#### CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER

- I, Anthony Pagano, certify that:
  - 1. I have reviewed this annual report on Form 20-F of Genmab A/S;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of Genmab A/S as of, and for, the periods presented in this report;
- 4. The other certifying officer of Genmab A/S and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for Genmab A/S and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to Genmab A/S, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of disclosure controls and procedures of Genmab A/S and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in internal control over financial reporting of Genmab A/S that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect internal control over financial reporting of Genmab A/S.
- 5. The other certifying officer of Genmab A/S and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the auditors of Genmab A/S and the audit committee of the board of directors of Genmab A/S (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the ability of Genmab A/S to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the internal control over financial reporting of Genmab A/S.

Date: March 29, 2021

/s/ Anthony Pagano

AMERICAS/2017215013.2

# PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Jan G. van de Winkel, President and Chief Executive Officer of Genmab A/S, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Annual Report on Form 20-F of Genmab A/S for the period ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Genmab A/S.

Date: March 29, 2021

/s/ Jan G. van de Winkel

AMERICAS/2017215013.2

# PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT T'O 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Anthony Pagano, Executive Vice President and Chief Financial Officer of Genmab A/S, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Annual Report on Form 20-F of Genmab A/S for the period ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Genmab A/S.

Date: March 29, 2021

/s/ Anthony Pagano

AMERICAS/2017215013.2



#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-253519 and 333-232693) of Genmab A/S of our report dated March 29, 2021 relating to the consolidated financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab Hellerup, Denmark March 29, 2021

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab, CVR-nr. 33 77 12 31 Strandvejen 44, DK-2900 Hellerup T: 3945 3945, www.pwc.dk