



## U.S. FDA Approves Kesimpta® (ofatumumab) in Relapsing Multiple Sclerosis

August 20, 2020

### Company Announcement

- Kesimpta® (ofatumumab) approved by U.S. FDA for the treatment of relapsing forms of multiple sclerosis in adults
- First B-cell therapy that can be self-administered using Sensoready® autoinjector pen
- Approval based on Phase III ASCLEPIOS I and II studies

**Copenhagen, Denmark; August 20, 2020 – Genmab A/S (Nasdaq: GMAB) announced today that the U.S. Food and Drug Administration (U.S. FDA) has approved the use of Kesimpta® (ofatumumab) injection for subcutaneous use, for the treatment of relapsing forms of multiple sclerosis (RMS) in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.**

Kesimpta is the first B-cell therapy that can be self-administered by patients at home using the Sensoready® autoinjector pen, once monthly after starting therapy. It is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG.

The approval was based on data from the Phase III ASCLEPIOS I and II trials, which investigated the efficacy and safety of monthly subcutaneous ofatumumab 20mg versus once daily oral teriflunomide 14mg in adults with RMS as well as the Phase II APLIOS study, which determined the bioequivalence of the subcutaneous delivery of ofatumumab via a pre-filled syringe and a Sensoready pen in patients with RMS. The results from the ASCLEPIOS studies were presented at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in September 2019 and were recently published in the August 6, 2020 issue of *The New England Journal of Medicine*. In December 2019 Novartis submitted the supplemental Biologics License Application (sBLA) for this indication to the U.S. FDA.

“This is a significant day for patients in the U.S. with relapsing multiple sclerosis, who will now have Kesimpta as an efficacious and convenient treatment option. We would like to thank the patients and investigators who took part in the trials that led to this approval as well as Novartis for their collaboration and their dedication, which has made ofatumumab available to an entirely new population of patients in need,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Today’s news does not impact Genmab’s 2020 financial guidance.

### About ASCLEPIOS

The ASCLEPIOS I and II studies (NCT02792218 and NCT02792231) are twin, identical design, flexible duration (up to 30 months), double-blind, randomized, multi-center Phase III studies evaluating the safety and efficacy of ofatumumab 20mg monthly subcutaneous injections versus teriflunomide 14mg oral tablets taken once daily in adults with a confirmed diagnosis of RMS<sup>1,2</sup>. The studies enrolled 1,882 patients with relapsing MS, between the ages of 18 and 55 years, with an Expanded Disability Status Scale (EDSS) score between 0 and 5.5<sup>1,2</sup>. The studies were conducted in over 350 sites in 37 countries.

The primary endpoint of both studies was to demonstrate that ofatumumab is superior to teriflunomide in reducing the frequency of confirmed relapses as evaluated by the ARR in patients treated up to 30 months<sup>1,2</sup>. Secondary endpoints included time to disability progression confirmed at three and six months respectively, confirmed disability improvement at six months, gadolinium enhancing T1 lesions, number of new or enlarging T2 lesions, serum levels of neurofilament light chain (NfL), and rate of brain volume loss<sup>1,2</sup>. Safety and the pharmacokinetic properties of ofatumumab were also all measured throughout the treatment period<sup>1,2</sup>.

### About APLIOS

The APLIOS study (NCT03560739) was a 12-week, open-label, Phase II bioequivalence study to determine the onset of B-cell depletion with ofatumumab subcutaneous monthly injections and the bioequivalence of subcutaneous administration of ofatumumab via a pre-filled syringe – as used in ASCLEPIOS I and II – and a Sensoready pen in patients with RMS. 284 patients were randomized according to injection device and site including the abdomen and the thigh. B-cell depletion was measured nine times over 12 weeks and Gd+ lesion counts were assessed at baseline and at Weeks 4, 8 and 12.<sup>3</sup>

### About Kesimpta® (ofatumumab)

Ofatumumab is a fully human CD20 monoclonal antibody (mAb) self-administered by a once-monthly subcutaneous injection in development for relapsing forms of multiple sclerosis (RMS). Kesimpta (ofatumumab) is approved in the U.S. for the treatment of RMS in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and is the first B-cell therapy that can be self-administered at home by patients using a Sensoready pen. Initial loading doses of Kesimpta are given on Days 1, 7 and 14, with the first injection performed under the guidance of a healthcare provider. Ofatumumab works by binding to the CD20 molecule on the B-cell surface and inducing potent B-cell lysis and depletion. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG.

### About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system characterized by myelin destruction and axonal damage of the brain, optic nerves and spinal cord<sup>4</sup>. MS disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss<sup>5</sup>. MS, which affects approximately 2.5 million people worldwide<sup>6</sup>, is often characterized into the following forms: primary progressive MS (PPMS) and relapsing forms of MS (RMS), which includes relapsing-remitting MS (RRMS) and secondary progressive MS (SPMS)<sup>7</sup>. Approximately 85% of

patients initially present with RMS<sup>8</sup>.

### About Genmab

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer. Founded in 1999, the company is the creator of the following approved antibodies: DARZALEX<sup>®</sup> (daratumumab, under agreement with Janssen Biotech, Inc.) for the treatment of certain multiple myeloma indications in territories including the U.S., Europe, Japan and China, Arzerra<sup>®</sup> (ofatumumab, under agreement with Novartis AG), for the treatment of certain chronic lymphocytic leukemia indications in the U.S., Japan and certain other territories, Kesimpta (subcutaneous ofatumumab, under agreement with Novartis AG), for the treatment of adults with relapsing forms of multiple sclerosis in the U.S. and TEPEZZA<sup>®</sup> (teprotumumab, under agreement with Roche granting sublicense to Horizon Therapeutics plc) for the treatment of thyroid eye disease in the U.S. A subcutaneous formulation of daratumumab, known in the U.S. as DARZALEX FASPRO<sup>™</sup> (daratumumab and hyaluronidase-fihj), has been approved in the U.S. and Europe for the treatment of adult patients with certain multiple myeloma indications. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. Genmab also has a broad clinical and pre-clinical product pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody<sup>®</sup> platform for generation of bispecific antibodies, the HexaBody<sup>®</sup> platform, which creates effector function enhanced antibodies, the HexElect<sup>®</sup> platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency and the DuoHexaBody<sup>®</sup> platform, which enhances the potential potency of bispecific antibodies through hexamerization. The company intends to leverage these technologies to create opportunities for full or co-ownership of future products. Genmab has alliances with top tier pharmaceutical and biotechnology companies. Genmab is headquartered in Copenhagen, Denmark with sites in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan.

### Contact:

Marisol Peron, Corporate Vice President, Communications & Investor Relations  
T: +1 609 524 0065; E: [mmp@genmab.com](mailto:mmp@genmab.com)

### For Investor Relations:

Andrew Carlsen, Senior Director, Investor Relations  
T: +45 3377 9558; E: [acn@genmab.com](mailto:acn@genmab.com)

*This Company Announcement contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with pre-clinical and clinical development of products, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products or technologies obsolete, and other factors. For a further discussion of these risks, please refer to the risk management sections in Genmab's most recent financial reports, which are available on [www.genmab.com](http://www.genmab.com) and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at [www.sec.gov](http://www.sec.gov). Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.*

Genmab A/S and/or its subsidiaries own the following trademarks: Genmab<sup>®</sup>; the Y-shaped Genmab logo<sup>®</sup>; Genmab in combination with the Y-shaped Genmab logo<sup>®</sup>; HuMax<sup>®</sup>; DuoBody<sup>®</sup>; DuoBody in combination with the DuoBody logo<sup>®</sup>; HexaBody<sup>®</sup>; HexaBody in combination with the HexaBody logo<sup>®</sup>; DuoHexaBody<sup>®</sup>; HexElect<sup>®</sup>; and UniBody<sup>®</sup>. Arzerra<sup>®</sup>, Sensoready<sup>®</sup> and Kesimpta<sup>®</sup> are trademarks of Novartis AG or its affiliates. DARZALEX<sup>®</sup> and DARZALEX FASPRO<sup>™</sup> are trademarks of Janssen Pharmaceutica NV. TEPEZZA<sup>™</sup> is a trademark of Horizon Therapeutics plc.

<sup>1</sup> ClinicalTrials.gov. Efficacy and Safety of Ofatumumab Compared to Teriflunomide in Patients With Relapsing Multiple Sclerosis (ASCLEPIOS I). <https://clinicaltrials.gov/ct2/show/NCT02792218>. Accessed January 2020.

<sup>2</sup> ClinicalTrials.gov. Efficacy and Safety of Ofatumumab Compared to Teriflunomide in Patients With Relapsing Multiple Sclerosis.(ASCLEPIOS II). <https://clinicaltrials.gov/ct2/show/NCT02792231>. Accessed January 2020.

<sup>3</sup> ClinicalTrials.gov. A 12 Week Randomized Open Label Parallel Group Multicenter Study to Evaluate Bioequivalence of 20 mg Subcutaneous Ofatumumab Injected by Pre-filled Syringe or Autoinjector in Adult RMS Patients <https://clinicaltrials.gov/ct2/show/NCT03560739>. Accessed May 2020

<sup>4</sup> Guthrie E. Multiple sclerosis: a primer and update. *Adv Studies Pharm.* 2007;4(11):313-317

<sup>5</sup> John Hopkins Medicine. Multiple sclerosis (MS). [https://www.hopkinsmedicine.org/neurology\\_neurosurgery/centers\\_clinics/multiple\\_sclerosis/conditions/index.html](https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/multiple_sclerosis/conditions/index.html). Accessed August 2019.

<sup>6</sup> GlobalData. EpiCast Report: Multiple Sclerosis - Epidemiology Forecast to 2026. Published November 2017.

<sup>7</sup> Multiple sclerosis international federation. Types of MS. <https://www.msif.org/about-ms/types-of-ms/>. Accessed August 2019

<sup>8</sup> Datamonitor. Multiple Sclerosis Treatment. Published August 2016.

Company Announcement no. 36  
CVR no. 2102 3884  
LEI Code 529900MTJPDPE4MHJ122

Genmab A/S  
Kalvebod Brygge 43  
1560 Copenhagen V  
Denmark

**Attachment**

- [200820\\_CA36\\_Kesimpta US Approval](#)