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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE MONTH OF AUGUST 2019**

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**COMMISSION FILE NUMBER 001-38976**

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**Genmab A/S**

(Exact name of Registrant as specified in its charter)

**Kalvebod Brygge 43  
1560 Copenhagen V  
Denmark  
+45 70 20 27 28**

(Address of principal executive offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1)

Yes  No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7)

Yes  No

This report on Form 6-K shall be deemed to be incorporated by reference in Genmab A/S's registration statements on Form S-8 (File No. 333-232693) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENMAB A/S

BY: /s/ David A. Eatwell

Name: David A. Eatwell

Title: Executive Vice President & Chief Financial Officer

**DATE: August 22, 2019**

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## EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	Company Announcement Dated August 22, 2019

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## Genmab Announces Approval of DARZALEX® (daratumumab) in Frontline Multiple Myeloma in Japan

### Company Announcement

- **DARZALEX® approved in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma ineligible for autologous stem cell transplant in Japan**
- **Genmab to receive USD 7 million milestone payment**
- **Approval based on data from Phase III ALCYONE study**

**Copenhagen, Denmark; August 22, 2019 – Genmab A/S (Nasdaq: GMAB) announced today that the Ministry of Health, Labor and Welfare (MHLW) in Japan has approved the use of DARZALEX (daratumumab) in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).** DARZALEX is being developed under an August 2012 agreement in which Genmab granted Janssen Biotech, Inc. (Janssen) an exclusive worldwide license to develop, manufacture and commercialize the product. Genmab will receive a USD 7 million milestone payment from Janssen in connection with the approval and first commercial sale of DARZALEX under the newly expanded label. The approval and related milestone do not impact the financial guidance issued by Genmab on August 14, 2019.

“Multiple myeloma remains one of the most common forms of blood cancer in Japan and as such, we are encouraged that patients in Japan newly diagnosed with this disease now have the option to receive a DARZALEX containing regimen,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The approval is based on data from the Phase III ALCYONE study that showed a reduction of the risk of disease progression or death by 50 percent in newly diagnosed ASCT ineligible multiple myeloma patients when daratumumab is combined with bortezomib, melphalan and prednisone. This data was presented as a Late-Breaking Abstract at the 2017 American Society of Hematology (ASH) Annual Meeting and published in *The New England Journal of Medicine* in December 2017.

### About the ALCYONE study

This Phase III study (NCT02195479) is a randomized, open-label, multicenter study that included 706 newly diagnosed patients with multiple myeloma who are ineligible for ASCT. Patients were randomized to receive 9 cycles of either VMP [bortezomib (a proteasome inhibitor), melphalan (an alkylating chemotherapeutic agent) and prednisone (a corticosteroid)] combined with daratumumab, or VMP alone. In the daratumumab treatment arm, patients received 16 mg/kg of daratumumab once weekly for six weeks (cycle 1; 1 cycle = 42 days), once every three weeks from cycles 2 to 9, once every four weeks from cycle 9 until disease progression. The primary endpoint of the study is progression free survival (PFS).

### About multiple myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells.<sup>1</sup> Approximately 6,313 new patients were expected to be diagnosed with multiple myeloma and approximately 4,338 people were expected to die from the disease in Japan in 2018.<sup>2</sup> Globally, it was estimated that 160,000 people were diagnosed and 106,000 died from the disease in 2018.<sup>3</sup> While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms which can include bone problems, low blood counts, calcium elevation, kidney problems or infections.<sup>4</sup>

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LEI Code 529900MTJPDPE4MHJ122



## Genmab Announces Approval of DARZALEX® (daratumumab) in Frontline Multiple Myeloma in Japan

### About DARZALEX® (daratumumab)

DARZALEX® (daratumumab) intravenous infusion is indicated for the treatment of adult patients in the United States: in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy; in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI); and as a monotherapy for the treatment of patients with multiple myeloma 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.<sup>5</sup> DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (U.S. FDA) approval to treat multiple myeloma. DARZALEX is indicated in Europe in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; for use in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy; and as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. The option to split the first infusion of DARZALEX over two consecutive days has been approved in both Europe and the U.S. In Japan, DARZALEX is approved in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adults with relapsed or refractory multiple myeloma and in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. DARZALEX is the first human CD38 monoclonal antibody to reach the market in the United States, Europe and Japan. For more information, visit [www.DARZALEX.com](http://www.DARZALEX.com).

Daratumumab is a human IgG1k monoclonal antibody (mAb) that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells. Daratumumab triggers a person's own immune system to attack the 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 (programmed cell death).<sup>5,6,7,8,9</sup>

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. A comprehensive clinical development program for daratumumab is ongoing, including multiple Phase III studies in smoldering, relapsed and refractory and frontline multiple myeloma settings. Additional studies are ongoing or planned to assess the potential of daratumumab in other malignant and pre-malignant diseases in which CD38 is expressed, such as amyloidosis, NKT-cell lymphoma and B-cell and T-cell ALL. Daratumumab has received two Breakthrough Therapy Designations from the U.S. FDA for certain indications of multiple myeloma, including as a monotherapy for heavily pretreated multiple myeloma and in combination with certain other therapies for second-line treatment of multiple myeloma.

### 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 has two approved antibodies, DARZALEX® (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications, other blood cancers and amyloidosis. A subcutaneous formulation of ofatumumab is in development for relapsing multiple sclerosis. 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® platform for generation of bispecific antibodies, the HexaBody® platform, which creates effector function enhanced antibodies, the HexElect® platform, which combines two co-dependently acting HexaBody

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molecules to introduce selectivity while maximizing therapeutic potency and the DuoHexaBody® 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 core sites in Utrecht, the Netherlands and Princeton, New Jersey, U.S.

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*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 Registration Statement on Form F-1 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®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; 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 AG or its affiliates. DARZALEX® is a trademark of Janssen Pharmaceutica NV.

<sup>1</sup> American Cancer Society. "Multiple Myeloma Overview." Available at <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Accessed June 2016.

<sup>2</sup> Globocan 2018. Japan Fact sheet. Available at <http://gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf> Accessed March 2019

<sup>3</sup> Globocan 2018. World Fact Sheet. Available at <http://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf>. Accessed December 2018.

<sup>4</sup> American Cancer Society. "How is Multiple Myeloma Diagnosed?" <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis>. Accessed June 2016.

<sup>5</sup> DARZALEX Prescribing information, July 2019. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/761036s019bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761036s019bl.pdf) Last accessed July 2019

<sup>6</sup> De Weers, M et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematological Tumors. *The Journal of Immunology*. 2011; 186: 1840-1848.

<sup>7</sup> Overdijk, MB, et al. Antibody-mediated phagocytosis contributes to the anti-tumor activity of the therapeutic antibody daratumumab in lymphoma and multiple myeloma. *MAbs*. 2015; 7: 311-21.

<sup>8</sup> Krejcik, MD et al. Daratumumab Depletes CD38+ Immune-regulatory Cells, Promotes T-cell Expansion, and Skews T-cell Repertoire in Multiple Myeloma. *Blood*. 2016; 128: 384-94.

<sup>9</sup> Jansen, JH et al. Daratumumab, a human CD38 antibody induces apoptosis of myeloma tumor cells via Fc receptor-mediated crosslinking. *Blood*. 2012; 120(21): abstract 2974.

