

## Genmab Announces Net Sales of DARZALEX<sup>®</sup> (daratumumab) for First Quarter of 2021

### Company Announcement

- Net sales of DARZALEX<sup>®</sup> in the first quarter of 2021 totaled USD 1,365 million
- Genmab receives royalties on worldwide net sales from Janssen Biotech, Inc.

Copenhagen, Denmark; April 20, 2021 – Genmab A/S (Nasdaq: GMAB) announced today that worldwide net trade sales of DARZALEX<sup>®</sup> (daratumumab), including sales of the subcutaneous formulation (sold under the tradename DARZALEX FASPRO<sup>®</sup> in the U.S.), as reported by Johnson & Johnson were USD 1,365 million in the first quarter of 2021. Net trade sales were USD 691 million in the U.S. and USD 674 million in the rest of the world. Genmab receives royalties on the worldwide net sales of DARZALEX and DARZALEX FASPRO under the exclusive worldwide license to Janssen Biotech, Inc. (Janssen) to develop, manufacture and commercialize daratumumab. As previously announced, Janssen is reducing its royalty payments to Genmab by what it claims to be Genmab's share of Janssen's royalty payments to Halozyme, cf. company announcement No. 39 of September 22, 2020.

### About DARZALEX<sup>®</sup> (daratumumab)

DARZALEX<sup>®</sup> (daratumumab) has become a backbone therapy in the treatment of multiple myeloma. DARZALEX intravenous infusion is indicated for the treatment of adult patients in the United States: in combination with carfilzomib and dexamethasone for the treatment of patients with relapsed/refractory multiple myeloma who have received one to three previous lines of therapy; in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; 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>1</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 for the treatment of adult patients in Europe via intravenous infusion or subcutaneous administration: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; 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 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<sup>2</sup>. Daratumumab is the first subcutaneous CD38 antibody approved in Europe for the treatment of multiple myeloma. 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 intravenous infusion is approved for the treatment of adult patients: in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple

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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 relapsed or refractory multiple myeloma. 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).

DARZALEX *FASPRO*<sup>®</sup> (daratumumab and hyaluronidase-fihj), a subcutaneous formulation of daratumumab, is approved in the United States for the treatment of adult patients with newly diagnosed light-chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone. It is also approved in the U.S. for the treatment of adult patients with multiple myeloma: in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for ASCT; in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for ASCT; in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for ASCT and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy; in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and as monotherapy, in 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.<sup>3</sup> DARZALEX *FASPRO* is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE<sup>®</sup> drug delivery technology. DARZALEX *FASPRO* is the first subcutaneous CD38 antibody approved in the U.S. for the treatment of multiple myeloma and the first and only approved treatment for patients with AL amyloidosis in the U.S.

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>1,4,5,6,7</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 and T-cell acute lymphocytic leukemia (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 an international biotechnology company with a core purpose to improve the lives of patients with cancer. Founded in 1999, Genmab is the creator of multiple approved antibody therapeutics that are marketed by its partners. The company aims to create, develop and commercialize differentiated therapies by leveraging next-generation antibody technologies, expertise in antibody biology, translational research and data sciences and strategic partnerships. To create novel therapies, Genmab utilizes its next-generation antibody technologies, which are the result of its collaborative company culture and a deep passion for innovation. Genmab's proprietary pipeline consists of modified antibody candidates, including bispecific T-cell engagers and next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. The company is headquartered in Copenhagen, Denmark with locations in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan. For more information, please visit [Genmab.com](http://Genmab.com).

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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>. DARZALEX<sup>®</sup> and DARZALEX FASPRO<sup>®</sup> are trademarks of Johnson & Johnson.

<sup>1</sup> DARZALEX Prescribing information, August 2020 [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/761036s029lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761036s029lbl.pdf)  
Last accessed August 2020

<sup>2</sup> DARZALEX Summary of Product Characteristics, available at <https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex>  
Last accessed June 2020

<sup>3</sup> DARZALEX FASPRO Prescribing information, January 2021. Available at:  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/761145s002lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761145s002lbl.pdf) Last accessed January 2021

<sup>4</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>5</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>6</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>7</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