



Genmab Announces Positive Topline Results in Phase III ANDROMEDA Study of Daratumumab in Light-chain (AL) Amyloidosis

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Company Announcement

- **Phase III ANDROMEDA study of subcutaneous daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone for patients with newly diagnosed light-chain (AL) amyloidosis met the primary endpoint of patients with hematologic complete response**
- **Janssen will discuss data with health authorities to prepare for regulatory filings**

Copenhagen, Denmark; May 28, 2020 – Genmab A/S (Nasdaq: GMB) announced today positive topline results from the Phase III ANDROMEDA (AMY3001) study of subcutaneous (SC) daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone (CyBorD) for patients with newly diagnosed light-chain (AL) amyloidosis. The study, conducted by Janssen Biotech, Inc. (Janssen), met the primary endpoint of percentage of patients with hematologic complete response. Patients in the study treated with daratumumab in combination with CyBorD had a 53.3% hematologic complete response compared to 18.1% of patients who were treated with CyBorD alone (odds ratio of 5.1 (95% CI 3.2 – 8.2, $p < 0.0001$)).

Overall, the safety profile of daratumumab SC in combination with CyBorD is consistent with the known safety profile of the CyBorD regimen and the known safety profile of daratumumab.

"We are very pleased with the topline results from the Phase III ANDROMEDA study in AL amyloidosis. We believe the data supports the potential of daratumumab in the treatment of this devastating, progressive disease, for which no approved treatments are available," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Janssen, which obtained an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab in 2012, will discuss with health authorities the potential for a regulatory submission for this indication.

About the ANDROMEDA (AMY3001) study

The Phase III study (NCT03201965) included 388 patients newly diagnosed with AL amyloidosis. Patients were randomized to receive treatment with either subcutaneous 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.

About Light-chain (AL) Amyloidosis

Amyloidosis is a disease that occurs when amyloid proteins, which are abnormal proteins, accumulate in tissues and organs. When the amyloid proteins cluster together, they form deposits that damage the tissues and organs. AL amyloidosis most frequently affects the heart, kidneys, liver, nervous system and digestive tract. There is currently no cure or existing approved therapies for AL amyloidosis though it can be treated with chemotherapy, dexamethasone, stem cell transplants and supportive therapies.¹ It is estimated that there are approximately 3,000 to 4,000 new cases of AL amyloidosis diagnosed annually in the U.S.²

About DARZALEX[®] (daratumumab)

DARZALEX[®] (daratumumab) intravenous infusion is indicated for the treatment of adult patients in the United States: 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.³ DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (U.S. FDA) approval to treat multiple myeloma. DARZALEX intravenous infusion is indicated for the treatment of adult patients in Europe: 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 therapy⁴. 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 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.

DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj), a subcutaneous formulation of daratumumab, is approved in the United States for the treatment of adult patients with multiple myeloma: 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.⁵ DARZALEX FASPRO is the first subcutaneous CD38-directed antibody approved in the U.S. for the treatment of multiple myeloma.

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).^{3,5,6,7,8,9}

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 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 three approved antibodies: DARZALEX® (daratumumab, under agreement with Janssen Biotech, Inc.) for the treatment of certain multiple myeloma indications in territories including the U.S., Europe and Japan, Arzerra® (ofatumumab, under agreement with Novartis AG), for the treatment of certain chronic lymphocytic leukemia indications in the U.S., Japan and certain other territories and TEPEZZA™ (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, DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj), has been approved in the U.S. 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. A subcutaneous formulation of ofatumumab is in development by Novartis for the treatment of 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 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 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

For Investor Relations:

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

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¹ Mayo Clinic website: www.mayoclinic.com/health/amyloidosis/DS00431

² Research and Markets, "Amyloidosis Treatment Market Size, Share & Trends Analysis Report by Treatment (Stem Cell Transplant, Chemotherapy, Supportive Care, Surgery, Targeted Therapy), By Country, And Segment Forecasts, 2018 - 2025

³ DARZALEX Prescribing information, April 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761036s027lbl.pdf Last

accessed April 2020

⁴ DARZALEX Summary of Product Characteristics, available at <https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex> Last accessed October 2019

⁵ DARZALEX FASPRO Prescribing information, May 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761145s000lbl.pdf Last accessed May 2020

⁶ 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.

⁷ 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.

⁸ 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.

⁹Jansen, 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

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Genmab A/S
Kalvebod Brygge 43
1560 Copenhagen V
Denmark

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