



Genmab Announces Phase III Study Exploring Daratumumab as Maintenance Treatment in Newly Diagnosed Multiple Myeloma

April 3, 2019

Company Announcement

- **Phase III study to examine daratumumab plus lenalidomide as maintenance treatment in patients with newly diagnosed multiple myeloma**
- **Study utilizes the subcutaneous formulation of daratumumab**
- **Study expected to start in the first half of 2019**

Copenhagen, Denmark; April 3, 2019 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that its collaboration partner, Janssen Biotech, Inc. (“Janssen”) plans to start a new Phase III study of daratumumab in multiple myeloma. The study (MMY3021) will compare subcutaneous daratumumab in combination with lenalidomide versus lenalidomide alone as maintenance treatment in patients with newly diagnosed multiple myeloma who are minimal residual disease (MRD) positive after frontline autologous stem cell transplant (ASCT). The primary end point of the study is MRD conversion rate, from MRD positive to MRD negative status, at twelve months. The study is planned to start in the first half of 2019. In August 2012, Genmab granted Janssen an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

“We are pleased to see Janssen’s continual commitment to evaluating the use of daratumumab in a wide array of settings and combinations. We are hopeful that the study will provide evidence of daratumumab’s potential to provide a benefit to patients with multiple myeloma beyond current standard of care treatments in the maintenance phase of treatment,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the MMY3021 study

The Phase III study is a randomized, open-label, multicenter study that will include up to 214 newly diagnosed patients with multiple myeloma who are MRD positive after autologous stem cell transplant and who have no prior anti-CD38 exposure. Patients will be randomized to receive either subcutaneous daratumumab in combination with lenalidomide or lenalidomide alone. In the daratumumab treatment arm, patients received 1,800 mg of subcutaneous daratumumab weekly for Cycles 1-2, every two weeks for Cycles 3-6 and every four weeks thereafter. Lenalidomide will be administered at 10 mg orally on days 1-28 with 15 mg given daily if it is well tolerated after three cycles. Both arms will continue until disease progression or for 36 cycles. The primary endpoint of the study is MRD-conversion at 12 months.

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.¹ Multiple myeloma is the third most common blood cancer in the U.S., after leukemia and lymphoma.² Approximately 26,000 new patients were expected to be diagnosed with multiple myeloma and approximately 13,650 people were expected to die from the disease in the U.S. in 2018.³ Globally, it was estimated that 160,000 people were diagnosed and 106,000 died from the disease in 2018.⁴ 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.⁵

About DARZALEX® (daratumumab)

DARZALEX® (daratumumab) injection for intravenous infusion is indicated in the United States 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.⁶ 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.

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.

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).^{6,7,8,9,10}

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 frontline multiple myeloma settings and in amyloidosis. Additional studies are ongoing or planned to assess the potential of daratumumab in other malignant and pre-malignant diseases, such as NKT-cell lymphoma, B and T-ALL. Daratumumab has received two Breakthrough Therapy Designations from the U.S. FDA, for multiple myeloma, as both a monotherapy and in combination with other therapies.

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 and other blood cancers. 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 and the HexElect® platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency. 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. For more information visit www.genmab.com.

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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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.

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

² National Cancer Institute. "A Snapshot of Myeloma." Available at www.cancer.gov/research/progress/snapshots/myeloma. Accessed June 2016.

³ Globocan 2018. United States of America Fact Sheet. Available at <http://gco.iarc.fr/today/data/factsheets/840-united-states-of-america-fact-sheets.pdf>. Accessed March 2019

⁴ Globocan 2018. World Fact Sheet. Available at <http://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf>. Accessed December 2018.

⁵ American Cancer Society. "How is Multiple Myeloma Diagnosed?" <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis>. Accessed June 2016.

⁶ DARZALEX Prescribing information, February 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761036s016bl.pdf Last accessed February 2019

⁷ 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.

⁸ 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.

⁹ 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.

¹⁰ 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.

1560 Copenhagen V
Denmark

Attachment

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