

Genmab Announces European Myeloma Network and Janssen Achieve Positive Topline Results from Phase 3 APOLLO Study of Daratumumab in Combination with Pomalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma

Company Announcement

- **Phase 3 APOLLO randomized study evaluating subcutaneous daratumumab in combination with pomalidomide and dexamethasone versus pomalidomide and dexamethasone alone in relapsed or refractory multiple myeloma met the primary endpoint of improving progression-free survival**
- **Janssen intends to discuss the data with health authorities for potential regulatory submissions**

Copenhagen, Denmark; July 31, 2020 – Genmab A/S (Nasdaq: GMAB) announced today that the European Myeloma Network (EMN) in collaboration with Janssen Research & Development, LLC (Janssen) reported positive results from the Phase 3 APOLLO (MMY3013) study of the subcutaneous (SC) formulation of daratumumab in combination with pomalidomide and dexamethasone (Pd) versus Pd alone as treatment for patients with relapsed or refractory multiple myeloma who have previously been treated with lenalidomide (an immunomodulatory drug) and a proteasome inhibitor (PI). The study met the primary endpoint of improving progression-free survival (PFS). Overall, the safety profile of daratumumab SC in combination with Pd was consistent with the safety profile for each therapy separately.

“We are pleased with these positive results for daratumumab, administered as a subcutaneous formulation, in combination with pomalidomide and dexamethasone. The corresponding intravenous regimen was previously approved by the U.S. FDA based on the Phase 1 single-arm EQUULEUS study,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Janssen Biotech, Inc., which obtained an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab in 2012, intends to discuss the data with health authorities in preparation for regulatory submissions and plans to submit the data for presentation at an upcoming medical conference.

The APOLLO study was designed to confirm the results from the Phase 1 EQUULEUS (MMY1001) study, which investigated intravenous (IV) daratumumab plus Pd in the same indication. In June 2017, the U.S. Food and Drug Administration (U.S. FDA) approved the use of DARZALEX in combination with Pd for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a PI based on the results of the EQUULEUS study.

About the APOLLO (MMY3013) study

This Phase 3 (NCT03180736), randomized, open-label, multicenter study included 304 patients with multiple myeloma who have previously been treated with lenalidomide and a PI. Patients were randomized 1:1 to either receive daratumumab in combination with Pd or Pd alone. In the original design of the study, patients in the daratumumab plus Pd arm were treated with the IV formulation of daratumumab. As of Amendment 1, all new subjects in the experimental arm were dosed with the SC formulation of daratumumab and patients who had already begun treatment with IV daratumumab had the option to switch to the SC formulation. The primary endpoint of the study was PFS. The study was conducted in Europe under an agreement between Janssen, EMN and Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON).

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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 estimated diagnosed with multiple myeloma and approximately 13,650 people were expected to have died 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) 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.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 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 therapy⁷. Daratumumab is the first subcutaneous CD38-directed 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 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.

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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.⁸ 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).^{6,9,10,11,12}

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, known as DARZALEX *FASPRO*[™] (daratumumab and hyaluronidase-fihj) in the U.S., 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. 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

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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.

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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>.

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, September 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761036s024lbl.pdf Last accessed September 2019

⁷ DARZALEX Summary of Product Characteristics, available at <https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex> Last accessed June 2020

⁸ DARZALEX FASPRO Prescribing information, May 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761145s000lbl.pdf Last accessed May 2020

⁹ 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.

¹⁰ 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.

¹¹ 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.

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¹²Jansen, 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.