

Company Announcement

Topline data from the randomized Phase II GRIFFIN study in transplant eligible, newly
diagnosed patients with multiple myeloma treated with daratumumab in combination with
lenalidomide, bortezomib, and dexamethasone met the study's primary endpoint with a
higher percentage of stringent complete response in the daratumumab arm as compared
with patients who received lenalidomide, bortezomib, and dexamethasone alone

Copenhagen, Denmark; July 8, 2019 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that topline data from the Phase II GRIFFIN (MMY2004) study of newly diagnosed patients with multiple myeloma eligible for high-dose chemotherapy and autologous stem cell transplantation (ASCT), who were treated with daratumumab in combination with lenalidomide, bortezomib, and dexamethasone (VRd), met its primary endpoint, demonstrating a higher percentage of stringent complete responses (sCR) than patients who received VRd alone. Specifically, the topline data showed that 42.4% of patients treated with daratumumab in combination with VRd achieved a sCR, compared to 32.0% of patients who received VRd alone, with an odds ratio of 1.57 (95% CI: 0.87 - 2.82, p=0.1359, exceeding the statistical significance at the pre-set 2-sided alpha level of 0.2). Secondary endpoints, including the results of the minimal residual disease (MRD) analysis, supported the primary endpoint favoring daratumumab in combination with VRd.

Overall, the safety profile of daratumumab in combination with VRd was consistent with the safety profile for each therapy separately, which has been reported from previous studies with the VRd regimen as well as previous studies with daratumumab.

Further analysis of the safety and efficacy data is ongoing, and Janssen Biotech, Inc., which licensed daratumumab from Genmab in 2012, plans to submit additional data for presentation at an upcoming medical conference.

"The data from the Phase II GRIFFIN trial underlines the potential of daratumumab when used in combination with VRd and supports Janssen's decision to start the PERSEUS and CEPHEUS Phase III studies of daratumumab in combination with VRd for certain frontline multiple myeloma indications," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "This data also builds on the efficacy and safety data for daratumumab as a frontline treatment for transplant-eligible multiple myeloma patients as seen in the CASSIOPEIA Phase III study in which newly diagnosed patients with multiple myeloma who were candidates for ASCT were treated with daratumumab combined with an immune-modulatory drug and a proteasome inhibitor."

About the GRIFFIN (MMY2004) study

This Phase II trial (NCT02874742) is a randomized, open label, parallel assignment study that included 223 patients with newly diagnosed multiple myeloma who were eligible for high-dose chemotherapy and autologous stem cell treatment. Patients were randomized to receive either daratumumab plus lenalidomide, bortezomib and dexamethasone, or lenalidomide, bortezomib and dexamethasone alone. The primary endpoint of the study is the number of patients who achieve sCR by the end of the consolidation treatment.

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. Multiple myeloma is the third most common blood cancer in the Genmab A/S

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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) 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.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 United States. In Japan, DARZALEX is approved in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for treatment of adults with relapsed or refractory multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market. 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 immunemodulatory 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-cell and T-cell 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, 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 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.

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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 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. 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.

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.

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.

¹ DARZALEX Prescribing information, June 2019. Available at:

https://www.accessdata.fda.gov/drugsatfda docs/label/2019/761036s020lbl.pdf Last accessed June 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.



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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.