Genmab Announces European Marketing Authorization for DARZALEX® (Daratumumab) in Combination with Bortezomib, Thalidomide and Dexamethasone in Frontline Multiple Myeloma

Company Announcement

- **DARZALEX® (daratumumab) approved in Europe in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant**
- **Approval follows positive opinion by European Committee for Medicinal Products for Human Use (CHMP) in December**
- **Approval based on data from Phase III CASSIOPEIA study**

Copenhagen, Denmark; January 20, 2020 – Genmab A/S (Nasdaq: GMAB) announced today that the European Commission (EC) has granted marketing authorization for DARZALEX® (daratumumab) in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT). The EC approval follows a positive opinion issued for DARZALEX by the CHMP of the European Medicines Agency (EMA) in December 2019. In August 2012, Genmab granted Janssen Biotech, Inc. (Janssen) an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"With this approval, newly diagnosed patients with multiple myeloma who are eligible for ASCT may have the opportunity for treatment with a DARZALEX-containing regimen. We are extremely pleased that DARZALEX has received this latest approval and we look forward to the combination of DARZALEX plus bortezomib, thalidomide and dexamethasone being launched in Europe," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The approval was based on the Phase III CASSIOPEIA (MMY3006) study sponsored by the French Intergroupe Francophone du Myelome (IFM) in collaboration with the Dutch-Belgian Cooperative Trial Group for Hematology Oncology (HOVON) and Janssen R&D, LLC. Data from this study was published in *The Lancet* and presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.

About the CASSIOPEIA (MMY3006) study
This Phase III study is a randomized, open-label, multicenter study, run by the French Intergroupe Francophone du Myelome (IFM) in collaboration with the Dutch-Belgian Cooperative Trial Group for Hematology Oncology (HOVON) and Janssen R&D, LLC, including 1,085 newly diagnosed subjects with previously untreated symptomatic multiple myeloma who are eligible for high dose chemotherapy and stem cell transplant. In the first part of the study, patients were randomized to receive induction and consolidation treatment with daratumumab combined with bortezomib, thalidomide (an immunomodulatory agent) and dexamethasone (a corticosteroid) or treatment with bortezomib, thalidomide and dexamethasone alone. The primary endpoint is the proportion of patients that achieve a stringent Complete Response (sCR). In the second part of the study, patients that achieved a response will undergo a second randomization to either receive maintenance treatment of daratumumab 16 mg/kg every 8 weeks for up to 2 years versus no further treatment (observation). The primary endpoint of this part of the study is progression free survival (PFS).

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] Approximately 16,830 new patients were expected to be diagnosed with multiple myeloma and approximately 10,480 people were expected to die from the disease in the Western Europe in 2018.[2] Globally, it was estimated that 160,000 people were diagnosed and 106,000 died from the disease in 2018.[3] 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.[4]

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.[5] 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 therapy[6]. 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, or bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma; 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 for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. 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).[5,6,7,8,9,10]

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 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

Genmab Announces European Marketing Authorization for DARZALEX® (Daratumumab) in Combination with Bortezomib, Thalidomide and Dexamethasone in Frontline Multiple Myeloma

CD38 is expressed, such as amyloidosis, NKT-cell lymphoma and B-cell and T-cell 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 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, 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 core sites in Utrecht, the Netherlands and Princeton, New Jersey, U.S.

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

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 or technologies 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 and the risk factors included in Genmab's final prospectus for our U.S. public offering and listing and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. 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.

[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] Globocan 2018. Western Europe Fact Sheet. Available at http://gco.iarc.fr/today/data/factsheets/populations/926-western-europe-fact-sheets.pdf Accessed March 2018

Genmab Announces European Marketing Authorization for DARZALEX® (Daratumumab) in Combination with Bortezomib, Thalidomide and Dexamethasone in Frontline Multiple Myeloma

[3] Globocan 2018. World Fact Sheet. Available at http://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf. Accessed December 2018.
[4] American Cancer Society. "How is Multiple Myeloma Diagnosed?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed June 2016
[5] DARZALEX Prescribing information, September 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761036s024lbl.pdf Last accessed September 2019
[6] DARZALEX Summary of Product Characteristics, available at https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex Last accessed October 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.