Genmab Announces Submission of Supplemental New Drug Application in Japan for Daratumumab in Combination with Lenalidomide and Dexamethasone in Frontline Multiple Myeloma

Media Release

Copenhagen, Denmark, April 5, 2019

- **Supplemental new drug application (sNDA) submitted in Japan for daratumumab in combination with lenalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are not candidates for high-dose chemotherapy and autologous stem cell transplant**
- **Submission based on data from Phase III MAIA study**

Genmab A/S (Nasdaq Copenhagen: GEN) announced today that Janssen Pharmaceutical K.K. has submitted a supplemental new drug application (sNDA) to the Ministry of Health, Labor and Welfare (MHLW) in Japan, for the use of daratumumab (DARZALEX®) in combination with lenalidomide and dexamethasone (Rd) as treatment for patients newly diagnosed with multiple myeloma who are not candidates for high-dose chemotherapy and autologous stem cell transplant (ASCT). The MHLW will grant a priority review of the application, based on the Orphan Drug Designation given to DARZALEX for patients with newly diagnosed multiple myeloma. In August 2012, Genmab granted Janssen an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"This marks the third major regulatory submission based on the MAIA data, following similar submissions earlier this year in the U.S. and Europe. The regulatory approvals will make daratumumab plus lenalidomide and dexamethasone a viable option for newly diagnosed multiple myeloma patients in these three major markets," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The submission is based on data from the Phase III MAIA study of daratumumab in combination with Rd as treatment for patients newly diagnosed with multiple myeloma, who are not candidates for high dose chemotherapy and ASCT. Data from the study was presented at the 60th American Society of Hematology Annual Meeting, which took place in San Diego, California in December 2018.

About the MAIA (MMY3008) study
The Phase III study (NCT02252172) is a randomized, open-label, multicenter study that includes 737 newly diagnosed patients with multiple myeloma who are not candidates for high-dose chemotherapy and ASCT. Patients were randomized to receive either daratumumab in combination with lenalidomide (an immunomodulatory drug) and dexamethasone (a corticosteroid) or lenalidomide and dexamethasone alone. In the daratumumab treatment arm, patients received 16 milligrams per kilogram (mg/kg) weekly for first 8 weeks (Cycles 1 and 2), every other week for 16 weeks (Cycles 3 to 6) and then every 4 weeks (Cycle 7 and beyond) until progression of disease or unacceptable toxicity. Lenalidomide is administered at 25 mg orally on days 1 through 21 of each 28-day cycle, and dexamethasone was administered at 40 mg once a week for both treatment arms. Participants in both treatment arms will continue Rd until disease progression or unacceptable toxicity. The primary endpoint of the study is 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 6,313 new patients were expected to be diagnosed with multiple myeloma and approximately 4,338 people were expected to die from the disease in Japan 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]

Genmab Announces Submission of Supplemental New Drug Application in Japan for Daratumumab in Combination with Lenalidomide and Dexamethasone in Frontline Multiple Myeloma

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.[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 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 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 immunomodulatory effects, in addition to direct tumor cell death, via apoptosis (programmed cell death).[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 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

Genmab Announces Submission of Supplemental New Drug Application in Japan for Daratumumab in Combination with Lenalidomide and Dexamethasone in Frontline Multiple Myeloma

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

This Media Release 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 Media Release 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. Japan Fact sheet. Available at http://gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf Accessed March 2019
[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, February 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761036s016lbl.pdf Last accessed February 2019
[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.
[9] 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.