Daratumumab Data Published in The Lancet Shows Encouraging Efficacy in Heavily Pretreated and Refractory Multiple Myeloma

Media Release

- **The Lancet published data from the Phase II study of daratumumab as a monotherapy to treat heavily pretreated and refractory multiple myeloma**
- **Updated data was presented at the American Society of Hematology Annual Meeting in December**

Copenhagen, Denmark; January 7, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today *The Lancet* has published data from the Phase II study (Sirius MMY2002) of daratumumab in patients with relapsed and refractory multiple myeloma. Patients that received 16 mg/kg of daratumumab had a median of five prior lines of therapy and 95.3% were refractory to both proteasome inhibitors (PIs) and immunomodulatory drugs, which are current standard of care treatments for multiple myeloma. The data showed a 29.2% overall response rate (31 of 106), including three stringent complete responses, ten very good partial responses, and 18 partial responses in patients treated with 16 mg/kg of daratumumab. The median time to response was one month among patients who responded to treatment. Median duration of response was 7.4 months, and median progression free survival was 3.7 months. The 12-month overall survival rate was 64.8% and at a subsequent cutoff, median overall survival was 17.5 months. Daratumumab was well tolerated, with fatigue (40%) and anemia (33%) of any grade as the most common adverse events (AEs). No drug-related AEs led to treatment discontinuation.

“Data from the daratumumab Sirius study illustrates the significant potential of daratumumab in patients with multiple myeloma who have undergone multiple rounds of prior treatment. Data from the study, now published in The Lancet, was the basis for the approval of daratumumab in heavily pre-treated or double refractory multiple myeloma by the U.S. FDA,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

In November 2015, the U.S. Food and Drug Administration (FDA) approved DARZALEX™ (daratumumab) injection for intravenous infusion for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.[1] A marketing application with data from the Sirius study and data from four other studies was submitted to the European Medicines Agency (EMA) by Janssen in September 2015 and was subsequently granted accelerated assessment.

About the Study (Sirius MMY2002)
This two-part study enrolled 124 patients who have received at least three prior lines of therapy, including both a proteasome inhibitor and an immunomodulatory agent, or who are double refractory to a proteasome inhibitor and an immunomodulatory agent. Examples of proteasome inhibitors are bortezomib or carfilzomib and examples of immunomodulatory agents are pomalidomide or lenalidomide. Part 1 defined an optimal daratumumab regimen going forward, while part 2 was an expansion, based on the optimal regimen determined in Part 1. The primary objective of the study was to define the optimal dose and dosing schedule, to determine the efficacy of two treatment regimens of daratumumab as measured by overall response rate (ORR), and to further characterize the safety of daratumumab as a single agent.

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 26,850 new patients will be diagnosed with multiple myeloma and approximately 11,240 people will die from the disease in the U.S. in 2015.[3] Globally, it is estimated that 124,225 people will be diagnosed and 87,084 will die from the disease in 2015.[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] Patients who relapse after treatment with standard therapies, including PIs or immunomodulatory agents, have poor prognoses and few treatment options.[6]

About DARZALEX™ (daratumumab)
DARZALEX™ (daratumumab) injection for intravenous infusion is indicated in the United States for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.[10] DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (FDA) approval to treat multiple myeloma. 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. It is believed to induce rapid tumor cell death through programmed cell death, or apoptosis,[7,10] and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,[7,10] antibody-dependent cellular phagocytosis[8,11] and antibody-dependent cellular cytotoxicity.[7,10] In addition, daratumumab therapy results in a reduction of immune-suppressive myeloid derived suppressor cells (MDSCs) and a subset of regulatory T cells (Tregs) both of which express CD38. These reductions in MDSCs and Tregs were paralleled by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow.[10]

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. Five Phase III clinical studies with daratumumab in relapsed and frontline settings are currently ongoing, and additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as smoldering myeloma and non-Hodgkin's lymphoma.

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, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and DARZALEX™ (daratumumab) for the treatment of heavily pretreated or double refractory multiple myeloma. Daratumumab is in clinical development for additional multiple myeloma indications and for non-Hodgkin's lymphoma. 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, and the HexaBody® platform which creates effector function enhanced antibodies. 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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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 in relation to actual results, unless required by law.

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