# Genmab Announces European Regulatory Submission for Daratumumab in Relapsed Multiple Myeloma

## Company Announcement

- **Application to broaden label for daratumumab for relapsed multiple myeloma submitted to EMA by Janssen**
- **Submission based on data from two Phase III studies, CASTOR and POLLUX**
- **Genmab to receive USD 10 million in milestone payments from Janssen**

**Copenhagen, Denmark; August 23, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that Janssen Pharmaceutica NV (Janssen) has submitted a variation to the Marketing Authorization to the European Medicines Agency (EMA) seeking to broaden the existing marketing authorization for daratumumab (DARZALEX®) to include treatment of adult patients with multiple myeloma who have received at least one prior therapy.** The submission of the application triggers milestone payments totaling USD 10 million to Genmab from Janssen. The milestone payments were included in Genmab's financial guidance for 2016 that was published on August 9, 2016. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"Daratumumab represents a new hope for people suffering from multiple myeloma, a disease which is presently incurable. We look forward to working together with Janssen and the EMA to making daratumumab available to a far wider group of patients," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The submission includes data from two Phase III studies: the CASTOR study of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma, and the POLLUX study of daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with relapsed or refractory multiple myeloma. The submission also included data from the Phase I study of daratumumab in combination with pomalidomide and dexamethasone in relapsed or refractory multiple myeloma.

Janssen submitted a supplemental Biologics License Application for daratumumab in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for treatment of patients with multiple myeloma who received at least one prior therapy to the U.S. Food and Drug Administration in August 2016.

**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 30,330 new patients are expected to be diagnosed with multiple myeloma and approximately 12,650 people are expected to die from the disease in the U.S. in 2016.[3] Globally, it was estimated that 124,225 people would be diagnosed and 87,084 would 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 proteasome inhibitors 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.[7] DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (FDA) approval to treat multiple myeloma. DARZALEX is indicated in

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Europe for use 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. 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,[7,8] and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,[7,8] antibody-dependent cellular phagocytosis[9,10] and antibody-dependent cellular cytotoxicity.[7,8] In addition, daratumumab therapy results in a reduction of immune-suppressive myeloid derived suppressor cells (MDSCs) and subsets of regulatory T cells (Tregs) and B cells (Bregs), all of which express CD38. These reductions in MDSCs, Tregs and Bregs were accompanied by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow.[7,11]

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, non-Hodgkin's lymphoma and a solid tumor.

**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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*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 in relation to actual results, unless required by law.*

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