

## Genmab Announces Positive Interim Result in Phase III Castor Study of Daratumumab in Relapsed or Refractory Multiple Myeloma

### Company Announcement

- Phase III Castor study of daratumumab in combination with bortezomib and dexamethasone in relapsed or refractory multiple myeloma met primary endpoint at pre-planned interim analysis
- IDMC recommended to stop the clinical trial early
- Data will be discussed with authorities to prepare for regulatory filings

Copenhagen, Denmark; March 30, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the Phase III Castor study (MMY3004) of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma met the primary endpoint of improving progression free survival (PFS) in an interim analysis ( $p = < 0.0001$ ). The planned interim analysis was conducted by an Independent Data Monitoring Committee (IDMC).

Daratumumab showed a tolerable safety profile in the interim analysis. Based on the IDMC's recommendation, the study will be stopped early. Patients originally assigned to the bortezomib plus dexamethasone treatment group will be offered the option of receiving daratumumab following confirmed disease progression. Patients will continue to be monitored for safety and overall survival. Further analysis of the safety and efficacy data is underway. Based on the interim data, Janssen Biotech, Inc., who licensed daratumumab from Genmab in 2012, will engage in a dialogue with health authorities about the potential for these data to serve as the basis for a regulatory submission for daratumumab in this indication.

"We are very pleased with the positive interim result in this study, which documents the therapeutic potential of daratumumab in combination with bortezomib and dexamethasone. We look forward to having the data presented at a future major medical conference," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

### About the study

The Phase III study includes approximately 490 patients who had relapsed or refractory multiple myeloma. Patients were randomized to receive either daratumumab combined with subcutaneous bortezomib (a type of chemotherapy, called a proteasome inhibitor) and dexamethasone (a corticosteroid), or bortezomib and dexamethasone alone. The primary endpoint 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.<sup>1</sup> Multiple myeloma is the third most common blood cancer in the U.S., after leukemia and lymphoma.<sup>2</sup> Approximately 26,850 new patients were estimated to be diagnosed with multiple myeloma and approximately 11,240 people would die from the disease in the U.S. in 2015.<sup>3</sup> Globally, it was estimated that 124,225 people would be diagnosed and 87,084 would die from the disease in 2015.<sup>4</sup> 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.<sup>5</sup> Patients who relapse after treatment with standard therapies, including proteasome inhibitors or immunomodulatory agents, have poor prognoses and few treatment options.<sup>6</sup>

### 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

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PI and an immunomodulatory agent.<sup>7</sup> 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](http://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,<sup>7,8</sup> and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,<sup>7,8</sup> antibody-dependent cellular phagocytosis<sup>9,10</sup> and antibody-dependent cellular cytotoxicity.<sup>7,8</sup> 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 paralleled by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow.<sup>7</sup>

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](http://www.genmab.com).

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