

Daratumumab Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration in Combination with Standard of Care Regimens for Previously Treated Multiple Myeloma

Company Announcement

- **Daratumumab receives Breakthrough Therapy Designation in combination with standard of care regimens for multiple myeloma patients who have received at least one prior line of therapy**
- **Potential for accelerated review**
- **Marks second Breakthrough Therapy Designation for daratumumab**

Copenhagen, Denmark; July 26, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for DARZALEX® (daratumumab) injection 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. Breakthrough Therapy Designation is a program intended to expedite the development and review of drugs to treat serious or life-threatening diseases in cases where preliminary clinical evidence shows that the drug may provide substantial improvements over available therapy. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab.

“This is the second time daratumumab has earned the distinction of a Breakthrough Therapy Designation. We are pleased that the FDA continues to recognize the potential of daratumumab to help patients with multiple myeloma. We continue to work with our strategic partner Janssen and the regulatory authorities to advance daratumumab to bring this treatment to more patients suffering from multiple myeloma as quickly as possible,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The Breakthrough Therapy Designation for daratumumab was granted on the basis of data from two Phase III studies: CASTOR (MMY3004; NCT02136134) evaluating daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone alone in patients with relapsed or refractory multiple myeloma, and POLLUX (MMY3003; NCT02076009) evaluating daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with relapsed or refractory multiple myeloma.

About Breakthrough Therapy Designation

The Breakthrough Therapy Designation was enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA) and is intended to expedite development of drugs to treat serious and life-threatening medical conditions when preliminary clinical evidence demonstrates that the drug may have substantial improvement on at least one clinically significant endpoint over available therapies. Breakthrough Therapy Designation includes all the features of the Fast Track Designation, as well as more intensive guidance from the FDA on a drug’s clinical development program.

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.¹ 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 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.

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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,^{1,2} and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,^{1,2} antibody-dependent cellular phagocytosis^{3,4} and antibody-dependent cellular cytotoxicity.^{1,2} 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.^{1,5}

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 indication.

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.

Genmab A/S and its subsidiaries own the following trademarks: Genmab®, the Y-shaped Genmab logo®, Genmab in combination with the Y-shaped Genmab logo™; the DuoBody logo®, the HexaBody logo™; HuMax®, HuMax-CD20®, DuoBody®, HexaBody® and UniBody®. Arzerra® is a trademark of Novartis AG or its affiliates. DARZALEX® is a trademark of Janssen Biotech, Inc.

¹ DARZALEX Prescribing Information, November 2015.

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² 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.

³ 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: 311-321.

⁴ Khagi, Y and Mark, TM. Potential role of daratumumab in the treatment of multiple myeloma. *Onco Targets Ther*. 2014; 7: 1095-1100.

⁵ Krejcik, MD et al. Daratumumab Depletes CD38+ Immune-regulatory Cells, Promotes T-cell Expansion, and Skews T-cell Repertoire in Multiple Myeloma. *Blood*. 2016; pii: blood-2015-12-687749. [Epub ahead of print].