

Genmab Announces Submission of U.S. & EU Regulatory Applications Seeking Approval of DARZALEX[®] (Daratumumab) Split Dosing Regimen

Media Release

- sBLA & Type II Variation submitted to U.S. FDA and the EMA respectively, seeking approval of split dosing regimen for DARZALEX
- Applications seek to update Prescribing Information and Summary of Product Characteristics
- Submissions supported by data from EQUULEUS (MMY1001) clinical trial

Copenhagen, Denmark; August 08, 2018 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that its licensing partner, Janssen Biotech, Inc., has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (U.S. FDA) and a Type II Variation to the European Medicines Agency (EMA) seeking approval of a split dosing regimen for DARZALEX[®] (daratumumab). The applications request to update the Prescribing Information and Summary of Product Characteristics in order to provide health care professionals the option of splitting the first infusion of DARZALEX over two consecutive days. The submissions are supported by data from the Phase Ib EQUULEUS (MMY1001) clinical trial, which demonstrated DARZALEX pharmacokinetics (PK) concentrations were comparable regardless of whether the first dose was administered as a split infusion or as a single first infusion in patients with multiple myeloma. The safety profile of DARZALEX was comparable when administered initially as either a split or a single dose. In August 2012, Genmab granted Janssen an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

“We are pleased that these submissions have been made in both the U.S. and Europe as, if approved, it would provide more flexibility of dosing for patients receiving DARZALEX, in connection with initial infusion,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the EQUULEUS (MMY1001) Study

The Phase Ib EQUULEUS open-label study includes up to 240 patients with the goal of evaluating the safety, tolerability and dose of daratumumab when administered in combination with various backbone treatment regimens for different settings of 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.⁶ 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 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. 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.

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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. 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).^{1,2,3,4,5}

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, myelodysplastic syndromes, 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, 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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Genmab A/S and/or its subsidiaries own the following trademarks: Genmab[®]; the Y-shaped Genmab logo[®]; Genmab in combination with the Y-shaped Genmab logo[®]; HuMax[®]; DuoBody[®]; DuoBody in combination with the DuoBody logo[®]; HexaBody[®]; HexaBody in combination with the HexaBody logo[®]; and UniBody[®]. Arzerra[®] is a trademark of Novartis AG or its affiliates. DARZALEX[®] is a trademark of Janssen Pharmaceutica NV.

¹ DARZALEX Prescribing information, May 2018. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761036s013lbl.pdf Last accessed May 2018

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.

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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: 311-21.

⁴ Krejci, 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.

⁵ 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.