

Data from Phase III ALCYONE Study of Daratumumab Accepted for Oral Presentation at Annual Meeting of the American Society of Hematology

Media Release

- Late-breaking abstract accepted for oral presentation
- Data from Phase III ALCYONE study of daratumumab in combination with bortezomib, melphalan and prednisone in front line multiple myeloma

Copenhagen, Denmark; November 21, 2017 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that data from the Phase III ALCYONE study of daratumumab in combination with bortezomib, melphalan and prednisone (VMP) versus VMP alone treating newly diagnosed multiple myeloma patients who are ineligible for autologous stem cell transplantation (ASCT), which was submitted by our collaboration partner Janssen Biotech, Inc., was accepted as a latebreaking abstract for oral presentation at the 59th Annual Meeting of the American Society of Hematology (ASH). The abstract is published online on the ASH website: www.hematology.org.

This data will be presented as part of the Late-Breaking Abstracts Session on December 12, 2017 at 8:15 AM EST (2:15 PM CET).

"We are very pleased that the exciting ALCYONE data in front line multiple myeloma has been chosen as one of the Late-Breaking abstracts to be presented at this year's prestigious ASH annual meeting, which shows that treatment with daratumumab reduced the risk of disease progression or death by 50%, compared to those in the study who did not receive daratumumab" said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the study

This Phase III study (NCT02195479) is a randomized, open-label, multicenter study and includes 706 newly diagnosed patients with multiple myeloma who are ineligible for autologous stem cell transplantation (ASCT). Patients were randomized to receive 9 cycles of either daratumumab combined with VMP [bortezomib (a proteasome inhibitor), melphalan (an alkylating chemotherapeutic agent) and prednisone (a corticosteroid)], or VMP alone. In the daratumumab treatment arm, patients received 16 mg/kg of daratumumab once weekly for six weeks (cycle 1; 1 cycle = 42 days), followed by once every three weeks (cycles 2-9). Following the 9 cycles, patients in the daratumumab treatment arm continued to receive 16 mg/kg of daratumumab once every four weeks until disease progression. The primary endpoint of the study is progression free survival (PFS).

About DARZALEX[®] (daratumumab)

DARZALEX® (daratumumab) injection for intravenous infusion is indicated in the United States 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. 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 in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, 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 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, for treatment of adults with relapsed or refractory

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multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market. For more information, visit <u>www.DARZALEX.com</u>.

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, including multiple Phase III studies, is ongoing with daratumumab in relapsed and frontline multiple myeloma 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, NKT-cell lymphoma, amyloidosis, myelodysplastic syndromes and solid tumors. 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, other blood cancers, and solid tumors. 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 <u>www.genmab.com</u>.

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¹ DARZALEX Prescribing information, June 2017. Available at: <u>https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761036s004lbl.pdf</u> Last accessed June 2017

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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: 311-21.

⁴ Krejcik, 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

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Media Release no. 08 Page 3/3 CVR no. 2102 3884 LEI Code 529900MTJPDPE4MHJ122