CHMP Issues Positive Opinion Recommending Subcutaneous Formulation of Daratumumab for the Treatment of Patients with Multiple Myeloma

Company Announcement

- **Committee for Medicinal Products for Human Use issued Positive Opinion for subcutaneous formulation of daratumumab for the treatment of patients with multiple myeloma**
- **Opinion based on data from Phase III COLUMBA and Phase II PLEIADES studies**

Copenhagen, Denmark; April 30, 2020 – Genmab A/S (Nasdaq: GMAB) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a Positive Opinion recommending the use of the subcutaneous formulation of daratumumab for the treatment of adult patients with multiple myeloma in frontline and relapsed / refractory settings. The CHMP's Positive Opinion for the subcutaneous formulation of daratumumab applies to all currently approved daratumumab indications in frontline and relapsed / refractory multiple myeloma settings. In August 2012, Genmab granted Janssen Biotech, Inc. (Janssen) an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"We are very pleased with this Positive Opinion from the CHMP as it potentially brings the convenient dosing of subcutaneous daratumumab closer to becoming available for multiple myeloma patients in Europe," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The Marketing Authorization Application for this formulation was submitted to the EMA by Janssen Pharmaceutica NV in July 2019 based on data from two studies: the Phase III non-inferiority COLUMBA (MMY3012) study, which compared the subcutaneous formulation of daratumumab to the intravenous formulation in patients with relapsed or refractory multiple myeloma, and data from the Phase II PLEIADES (MMY2040) study, which is evaluating subcutaneous daratumumab in combination with certain standard multiple myeloma regimens. The topline results from the COLUMBA data were announced in February 2019 and subsequently presented in oral sessions at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and the 24th European Hematology Association (EHA) Annual Congress. Updated data of the COLUMBA and the PLEIADES studies were presented during poster sessions at the 61st American Society of Hematology (ASH) Annual Meeting in December 2019.

About the COLUMBA (MMY3012) study
The Phase III trial (NCT03277105) is a randomized, open-label, parallel assignment study that included 522 adults diagnosed with relapsed and refractory multiple myeloma. Patients were randomized to receive either: subcutaneous (SC) daratumumab, as 1800 mg daratumumab with rHuPH20 2000 U/mL once weekly in Cycle 1 and 2, every two weeks in Cycles 3 to 6, every 4 weeks in Cycle 7 and thereafter until disease progression, unacceptable toxicity or the end of study; or 16 mg/kg IV daratumumab once weekly in Cycle 1 and 2, every two weeks in Cycles 3 to 6, every 4 weeks in Cycle 7 and thereafter until disease progression, unacceptable toxicity or the end of study. The co-primary endpoints of the study are overall response rate and Maximum trough concentration of daratumumab (C_{trough}; defined as the serum pre-dose concentration of daratumumab on Cycle 3 Day 1).

About the PLEIADES (MMY2040) study
The Phase II trial (NCT03412565) is a non-randomized, open-label, parallel assignment study that includes 265 adults either newly diagnosed or with relapsed or refractory multiple myeloma. Patients with newly diagnosed multiple myeloma are being treated with 1,800 mg SC daratumumab in combination with either bortezomib, lenalidomide and dexamethasone (D-VRd) or bortezomib, melphalan and prednisone (D-VMP). Patients with relapsed or refractory multiple myeloma are being treated with 1,800 mg SC daratumumab plus lenalidomide and dexamethasone (D-Rd). An additional cohort of patients with relapsed and refractory multiple myeloma treated with daratumumab plus carfilzomib and dexamethasone

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(D-Kd) was subsequently added to the study. The primary endpoint for the D-VMP, D-Kd and D-Rd cohorts is overall response rate. The primary endpoint for the D-VRd cohort is very good partial response or better rate.

About DARZALEX® (daratumumab)
DARZALEX® (daratumumab) intravenous infusion is indicated for the treatment of adult patients in the United States: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; 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.[1] DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (U.S. FDA) approval to treat multiple myeloma. DARZALEX intravenous infusion is indicated for the treatment of adult patients in Europe: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; 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[2]. The option to split the first infusion of DARZALEX over two consecutive days has been approved in both Europe and the U.S. In Japan, DARZALEX intravenous infusion is approved for the treatment of adult patients: in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma; 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 for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. DARZALEX is the first human CD38 monoclonal antibody to reach the market in the United States, Europe and Japan. 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. 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).[1,2,3,4,5,6]

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 refractory and frontline multiple myeloma settings. Additional studies are ongoing or planned to assess the potential of daratumumab in other malignant and pre-malignant diseases in which CD38 is expressed, such as amyloidosis, NKT-cell lymphoma and T-cell ALL. Daratumumab has received

two Breakthrough Therapy Designations from the U.S. FDA for certain indications of multiple myeloma, including as a monotherapy for heavily pretreated multiple myeloma and in combination with certain other therapies for second-line treatment of multiple myeloma.

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 is the creator of three approved antibodies: DARZALEX® (daratumumab, under agreement with Janssen Biotech, Inc.) for the treatment of certain multiple myeloma indications in territories including the U.S., Europe and Japan, Arzerra® (ofatumumab, under agreement with Novartis AG), for the treatment of certain chronic lymphocytic leukemia indications in the U.S., Japan and certain other territories and TEPEZZA™ (teprotumumab, under agreement with Roche granting sublicense to Horizon Therapeutics plc) for the treatment of thyroid eye disease in the U.S. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. A subcutaneous formulation of ofatumumab is in development by Novartis for the treatment of 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, the HexaBody® platform, which creates effector function enhanced antibodies, the HexElect® platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency and the DuoHexaBody® platform, which enhances the potential potency of bispecific antibodies through hexamerization. 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. Genmab is headquartered in Copenhagen, Denmark with sites in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan.

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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 or technologies 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 and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

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[1] DARZALEX Prescribing information, September 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761036s024lbl.pdf Last accessed September 2019
[2] DARZALEX Summary of Product Characteristics, available at https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex Last accessed October 2019
[3] 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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[6] 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