CHMP Issues Positive Opinion Recommending DARZALEX® (daratumumab) for Front Line Multiple Myeloma

Company Announcement

- **CHMP issued positive opinion for DARZALEX for front line multiple myeloma**
- **Final decision from European Commission expected in the coming months**
- **Opinion based on data from Phase III ALCYONE study**

Copenhagen, Denmark; July 27, 2018 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending broadening the existing marketing authorization for DARZALEX® (daratumumab) in the European Union. The recommendation is for the use of DARZALEX® (daratumumab) in combination with bortezomib, melphalan and prednisone (VMP) for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT). The Type II variation application was submitted to the EMA by Genmab's licensing partner, Janssen Biotech, Inc., in November 2017. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"We are very pleased to receive this positive opinion from the CHMP, as it is an important step towards potentially bringing daratumumab to an expanded number of patients throughout Europe," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The positive opinion of the CHMP was based on data from the Phase III ALCYONE study that showed a reduction of the risk of disease progression or death by 50 percent (Hazard Ratio [HR] = 0.50; 95 percent CI [0.38-0.65], p<0.0001) in patients with newly diagnosed multiple myeloma ineligible for ASCT when daratumumab is combined with VMP. The safety of DARZALEX combination therapy was consistent with the known safety profiles of DARZALEX monotherapy and of therapy with bortezomib, melphalan and prednisone, respectively. This data was presented as a Late-Breaking Abstract at the 2017 American Society of Hematology (ASH) Annual Meeting and simultaneously published in The New England Journal of Medicine in December, 2017.

A CHMP opinion is one of the final steps in the regulatory process of the EMA. A final decision by the European Commission is anticipated within approximately two months.

About the ALCYONE study
This Phase III study (NCT02195479) is a randomized, open-label, multicenter study that included 706 newly diagnosed patients with multiple myeloma who are ineligible for ASCT. Patients were randomized to receive 9 cycles of either VMP [bortezomib (a proteasome inhibitor), melphalan (an alkylating chemotherapeutic agent) and prednisone (a corticosteroid)] combined with daratumumab, 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), once every three weeks from cycles 2 to 9, and once every 4 weeks from cycle 9 until disease progression. 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.[1] Multiple myeloma is the third most common blood cancer in the U.S., after leukemia and lymphoma.[2] Approximately 30,770 new patients are expected to be diagnosed with multiple myeloma and approximately 12,770 people are expected to die from the disease in the U.S. in 2018.[3] Globally, it was estimated that 124,225 people would be diagnosed and 87,084 would die from the disease in 2015.[4] 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.[5]

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.

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).[6,7,8,9,10]

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.

CHMP Issues Positive Opinion Recommending DARZALEX® (daratumumab) for Front Line Multiple Myeloma

Contact:
Rachel Curtis Gravesen, Senior Vice President, Investor Relations & Communications
T: +45 33 44 77 20; M: +45 25 12 62 60; E: rcg@genmab.com

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 to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

[1] American Cancer Society. "Multiple Myeloma Overview." Available at http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma.Accessed June 2016.
[2] National Cancer Institute. "A Snapshot of Myeloma." Available at www.cancer.gov/research/progress/snapshots/myeloma. Accessed June 2016.
[3] American Cancer Society. "What are the key statistics about multiple myeloma?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-key-statistics. Accessed March 2018
[4] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of New Cancers in 2015. Available at: http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=17270&Text-c=Multiple+myeloma&pYear=3&type=0&window=1&submit=%C2%A0Execute. Accessed June 2016.
[5] American Cancer Society. "How is Multiple Myeloma Diagnosed?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed June 2016.
[6] DARZALEX Prescribing information, May 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761036s013lbl.pdf Last accessed May 2018
[7] 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.
[8] 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.
[9]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.
[10]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.