# Genmab Announces European Marketing Authorization for DARZALEX® (daratumumab) for Front Line Multiple Myeloma

## Company Announcement

- **DARZALEX approved in Europe in combination with bortezomib, melphalan and prednisone in patients with newly diagnosed multiple myeloma**
- **Approval follows positive opinion by European Committee for Medicinal Products for Human Use (CHMP) in July**
- **Genmab to receive milestone payment of USD 13 million from Janssen upon first sale of DARZALEX in the newly approved indication**

**Copenhagen, Denmark; August 31, 2018 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the European Commission (EC) has granted marketing authorization for 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 EC approval follows a positive opinion issued for DARZALEX by the CHMP of the European Medicines Agency (EMA) in July 2018. In August 2012, Genmab granted Janssen Biotech, Inc. (Janssen) an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

Genmab will receive a milestone payment of USD 13 million from Janssen in connection with the first commercial sales of DARZALEX under the expanded label. The sales are expected to occur quickly after the approval. This milestone payment was included in the financial guidance issued by Genmab originally on February 21, 2018 and then reiterated in subsequent quarterly financial reports, most recently on August 8, 2018, and as such there is no change to the company's financial guidance following this approval.

"Approved in this indication in the U.S. since early May, DARZALEX in combination with bortezomib, melphalan and prednisone will now become an option for newly diagnosed multiple myeloma patients in Europe," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We are very pleased that many more patients in need will have the opportunity for treatment with this regimen and we look forward to seeing this combination launched in Europe."

The positive opinion of the CHMP was based on data from the Phase III ALCYONE (MMY3007) 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.

### 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

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Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells.[1] Approximately 35,433 new patients were diagnosed with multiple myeloma and approximately 22,060 people died from the disease in Western Europe in 2016.[3] Globally, it was estimated that 138,509 people were diagnosed and 98,437 died from the disease in 2016.[3] 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.[4]

**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.[5] 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).[5,6,7,8,9]

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

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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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