Genmab Announces Positive Topline Results in Phase III ALCYONE Study of Daratumumab in Front Line Multiple Myeloma

Company Announcement

- **Phase III ALCYONE study of daratumumab in combination with bortezomib, melphalan and prednisone (VMP) in front line multiple myeloma met the primary endpoint at a pre-planned interim analysis**
- **Independent Data Monitoring Committee recommends unblinding the data**
- **Data will be discussed with health authorities to prepare for regulatory filings**

Copenhagen, Denmark; August 24, 2017 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today topline results from the Phase III ALCYONE study (MMY3007) of daratumumab in combination with bortezomib, melphalan and prednisone (VMP) versus VMP alone as front line treatment for newly diagnosed patients who are not considered candidates for autologous stem cell transplantation (ASCT). The study met the primary endpoint of improving progression free survival (PFS) at a pre-planned interim analysis (Hazard Ratio (HR) = 0.50 (95% CI 0.38-0.65), $p < 0.0001$). Treatment with daratumumab reduced the risk of disease progression or death by 50%, as compared to those who did not receive daratumumab. The median PFS for patients treated with daratumumab in combination with VMP has not been reached, compared to an estimated median PFS of 18.1 months for patients who received VMP alone.

Overall, the safety profile of daratumumab in combination with VMP is consistent with the known safety profile of the VMP regimen and the known safety profile of daratumumab.

Based on the results at the pre-planned interim analysis conducted by an Independent Data Monitoring Committee (IDMC), it was recommended that the data be unblinded. All patients will continue to be monitored for safety and overall survival. Further analysis of the safety and efficacy data is underway and Janssen Biotech, Inc., which licensed daratumumab from Genmab in 2012, will discuss with health authorities the potential for a regulatory submission for this indication. The data are expected to be submitted for presentation at an upcoming medical conference and for publication in a peer-reviewed journal.

“The interim results of the ALCYONE study yet again illustrate the potential of daratumumab in multiple myeloma in combination with existing treatment regimens; this time with VMP in the front line setting. We are very pleased with the outcome of the pre-planned interim analysis in this study, which adds further to our hope that daratumumab could potentially become the critical driver redefining combination treatment in multiple myeloma,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Today’s news does not impact Genmab’s 2017 financial guidance.

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).

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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 30,330 new patients were expected to be diagnosed with multiple myeloma and approximately 12,650 people were expected to die from the disease in the U.S. in 2016.[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] Patients who relapse after treatment with standard therapies, including proteasome inhibitors or immunomodulatory agents, have poor prognoses and few treatment options.[6]

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.[7] 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 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. DARZALEX is the first human CD38 monoclonal antibody approved in Europe. 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).[7,8,9,10,11]

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. Five Phase III clinical studies 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 www.genmab.com.

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