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...
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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 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).5,7,8,9,10

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 preclinical 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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Genmab A/S and/or its subsidiaries own the following trademarks: Genmab®, the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®, DuoBody®, DuoBody in combination with the DuoBody logo®; HexaBody®, HexaBody in combination with the HexaBody logo®; and UniBody®. Arzerra® is a trademark of Novartis AG or its affiliates. DARZALEX® is a trademark of Janssen Pharmaceutica NV.

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.