

Genmab Announces New Phase III Combination Study of Daratumumab in Multiple Myeloma

Company Announcement

- Phase III study of daratumumab in combination with pomalidomide and dexamethasone in relapsed and refractory multiple myeloma
- Collaborative study between European Myeloma Network and Janssen
- Study expected to start Q2 2017

Copenhagen, Denmark; April 28, 2017 – Genmab A/S (OMX: GEN) announced today that Janssen Research & Development, LLC, in collaboration with the European Myeloma Network (EMN) and Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON), plans to start a Phase III study of daratumumab in relapsed and refractory multiple myeloma. The study (MMY3013, APOLLO) is a randomized Phase III that will compare daratumumab in combination with pomalidomide and dexamethasone versus pomalidomide and dexamethasone in patients who have previously been treated with an immunomodulatory drug and a proteasome inhibitor (PI). The study is expected to start in Q2 2017 and is designed to confirm results from the MMY1001 (EQUULEUS) study, a Phase I study investigating the daratumumab-pomalidomide-dexamethasone combination, are currently under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) date of June 17, 2017.

“We are very pleased to see this Phase III study initiated. The combination of daratumumab with pomalidomide and dexamethasone may represent a new approach for patients who have been previously treated with an immunomodulatory drug and a PI. We look forward to the readout of this study,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the MMY3013 (APOLLO) study

This is a Phase III, randomized, open-label, multicenter study and will include approximately 354 patients with multiple myeloma who have previously been treated with an immunomodulatory drug and a PI. Patients will be randomized 1:1 to either receive daratumumab in combination with pomalidomide and dexamethasone or pomalidomide and dexamethasone alone. The primary endpoint of the study is progression-free survival (PFS). The study will be conducted in Europe by the European Myeloma Network in collaboration with Janssen.

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 and as a monotherapy for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (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 (FDA) approval to treat multiple myeloma. DARZALEX is indicated in Europe 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 for use 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. 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}

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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, NK/T-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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Genmab A/S and its subsidiaries own the following trademarks: Genmab[®]; the Y-shaped Genmab logo[®]; Genmab in combination with the Y-shaped Genmab logo[™]; the DuoBody logo[®]; the HexaBody logo[™]; HuMax[®]; HuMax-CD20[®]; DuoBody[®]; HexaBody[®] and UniBody[®]. Arzerra[®] is a trademark of Novartis AG or its affiliates. DARZALEX[®] is a trademark of Janssen Biotech, Inc.

¹ FDA 2015. Daratumumab Prescribing information. Available at:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/761036Orig1s000bledt.pdf. Last accessed December 2016.

² 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.

³ 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.

⁴ Krejciak, 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.

⁵ 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.