

Genmab Announces Studies of Daratumumab in Combination with Atezolizumab in a Solid Tumor and Multiple Myeloma

Company Announcement

- Phase lb studies of daratumumab in combination with Roche's immune checkpoint inhibitor atezolizumab in a solid tumor and multiple myeloma to be started
- Studies conducted under a clinical trial collaboration agreement between Janssen and Roche

Copenhagen, Denmark; March 21, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that daratumumab will be investigated in early stage clinical studies in combination with atezolizumab (anti-PD-L1 antibody), in a solid tumor and multiple myeloma. The studies will be conducted under a clinical trial collaboration agreement between Genmab's licensing partner for daratumumab, Janssen Biotech, Inc., and Genentech, a member of the Roche Group. Atezolizumab is an investigational monoclonal antibody designed to bind to a protein called PD-L1, which is expressed on tumor cells and tumor-infiltrating immune cells. Janssen will conduct a Phase Ib study of daratumumab in combination with atezolizumab to treat a solid tumor. Genentech will amend an ongoing Phase Ib study to assess atezolizumab in combination with daratumumab, with daratumumab and lenalidomide, and with daratumumab and pomalidomide in relapsed/refractory multiple myeloma (NCT02431208). The studies are expected to start enrolling patients later this year and information about the studies will be posted on www.clinicaltrials.gov.

"We are very excited about the start of the first study to investigate daratumumab in a solid tumor, potentially expanding its clinical utility beyond hematological cancers. We are equally excited about testing daratumumab in combination with an immune checkpoint inhibitor, such as Roche's anti-PDL1, atezolizumab, in multiple myeloma. Both studies mark a key next step in the expansive clinical development of daratumumab in the hope to find even more effective treatment options for cancer patients," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About DARZALEX[®] (daratumumab)

DARZALEX[®] (daratumumab) injection for intravenous infusion is indicated in the United States 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. 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. It is believed to induce rapid tumor cell death through programmed cell death, or apoptosis,^{1,2} and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,^{1,2} antibody-dependent cellular phagocytosis^{3,4} and antibody-dependent cellular cytotoxicity.^{1,2} In addition, daratumumab therapy results in a reduction of immune-suppressive myeloid derived suppressor cells (MDSCs) and a subset of regulatory T cells (Tregs) and B cells (Bregs), all of which express CD38. These reductions in MDSCs, Tregs, and Bregs were paralleled by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow.¹

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 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 and non-Hodgkin's lymphoma.

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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, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and DARZALEX® (daratumumab) for the treatment of heavily pretreated or double refractory multiple myeloma. Daratumumab is in clinical development for additional multiple myeloma indications and for non-Hodgkin's lymphoma. 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 DARZALEX Prescribing Information, November 2015.

² De Weers 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 Overjijk 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 Khagi and Mark. Potential role of daratumumab in the treatment of multiple myeloma. Onco Targets Ther. 2014; 7: 1095–1100.