Phase II Study of Daratumumab in Non-Hodgkin’s Lymphoma Will Not Proceed to Stage 2 of Trial

Company Announcement

- Phase II study (CARINA, LYM2001) in NHL will not proceed
- Other ongoing and planned studies with daratumumab in lymphomas and other cancers outside multiple myeloma continue as planned

Copenhagen, Denmark; March 30, 2017 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that its collaboration partner for daratumumab, Janssen Biotech, Inc., has decided not to initiate stage 2 of the Phase II study (CARINA, LYM2001) of daratumumab in three types of relapsed or refractory non-Hodgkin’s lymphoma (NHL). The study will not proceed to stage 2 as a data review showed that two cohorts of the study, investigating the use of daratumumab monotherapy in relapsed or refractory patients with follicular lymphoma (FL), and with diffuse large B-cell lymphoma (DLBCL) did not reach the predefined futility thresholds of overall response rates (ORR) of 50%, and 30%, respectively. In the third cohort in the study, patients with mantle cell lymphoma (MCL), ORR was not evaluable due to slow recruitment, driven by the aggressive nature of the disease in its final stages. This has no impact on other ongoing or planned studies with daratumumab.

“While we hoped that daratumumab as a monotherapy could potentially provide a new treatment option in NHL patients with a high unmet medical need, the preliminary activity profile seen was not sufficient for the study to continue. Daratumumab is still being investigated in a number of indications including multiple myeloma and other hematological cancers such as NK/T-cell lymphoma and myelodysplastic syndrome as well as in solid tumors,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the CARINA LYM2001 study
The Phase II study (NCT02413489) is a three arm (DLBCL, FL, MCL), open-label multicenter study, which planned to enroll up to 210 patients in 2 stages with relapsed or refractory non-Hodgkin’s lymphoma. Stage 1 of the study was designed to provide a preliminary assessment of monotherapy activity, with stage 2 designed to further evaluate safety and efficacy of daratumumab monotherapy. Stage 2 will now not proceed. The primary endpoint of the study was overall response rate. The safety profile of daratumumab in these diseases was also assessed.

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 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).²,³,⁴,⁵

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
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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.

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.