

Genmab Announces that Janssen Will Stop Studies of Daratumumab in Combination with Anti-PD-(L)1

Company Announcement

- Based on a recent planned review, the Data Monitoring Committee (DMC) recommends Phase Ib/II study of daratumumab plus atezolizumab (anti PD-L1 antibody) in patients with previously treated non-small cell lung cancer to be terminated.
- Phase I MMY2036 study of daratumumab plus JNJ-63723283 (anti PD-1 antibody) in patients with multiple myeloma, discontinued
- Health Authorities have been informed about these events and Janssen has contacted its partner companies conducting daratumumab and anti-PD-(L)1 combination studies to discuss ceasing enrollment and dosing of the combination while the data is being further investigated

Copenhagen, Denmark; May 26, 2018 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that following a planned review, the DMC has recommended that the Phase Ib/II study (CALLISTO/LUC2001) of daratumumab in combination with atezolizumab versus atezolizumab monotherapy in patients with previously treated advanced or metastatic non-small cell lung cancer should be terminated. In addition the phase I MMY2036 study of daratumumab plus JNJ-63723283, an anti PD-1 antibody in patients with multiple myeloma will be discontinued.

The DMC determined that there was no observed benefit within the combination treatment arm, daratumumab plus atezolizumab, over atezolizumab monotherapy, and recommended termination of the study. In addition to the lack of benefit, the DMC noted a numerical increase in mortality-related events in the combination arm.

Based on these findings, Janssen has made the decision also to discontinue the MMY2036 study, which was evaluating a combination of daratumumab and anti-PD-1 (JNJ-63723283) in patients with Multiple Myeloma. Janssen has informed Health Authorities about these events and has contacted its partner companies conducting daratumumab and anti-PD-(L)1 combination studies to discuss ceasing enrollment and dosing of the combination while the data is being further investigated.

In August 2012, Genmab granted Janssen an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

“While we are disappointed that the studies will be discontinued, Genmab fully supports Janssen’s decision as patient safety is paramount in drug development. We look forward to gaining a better understanding of the data upon further analysis. We are pleased that the development program for daratumumab remains expansive and continues to benefit patients with Multiple Myeloma” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the LUC2001 study

This randomized, multicenter, Phase Ib/II study includes 98 patients with previously treated advanced or metastatic NSCLC. Patients will be randomized to receive daratumumab at 16 milligrams per kilogram (mg/kg) weekly for 3 cycles and on day 1 of every 21-day cycle thereafter. Atezolizumab will be administered at 1,200 mg on day 2 of Cycle 1 and on day 1 of every 21-day cycle thereafter. Patients will continue to receive treatment until disease progression or unacceptable toxicity. Patients in the atezolizumab monotherapy arm with confirmed disease progression will be eligible to crossover to the daratumumab plus atezolizumab arm, if they meet the crossover eligibility criteria. The primary endpoint

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of the study is percentage of patients with ORR, defined as percentage of patients with PR or CR as defined by Response Evaluation Criteria in Solid Tumors (RECIST).

About MMY2036 study

This randomized, multicenter, multiphase study includes up to 386 patients with relapsed or refractory multiple myeloma. Approximately 6 subjects will be enrolled in Part 1 (a safety run-in cohort) followed by 80 subjects randomly assigned in a 1:1 ratio to the 2 treatment arms in Part 2 (Phase 2). After all subjects in Part 2 are followed-up for approximately 4 months, it will be determined, based on review of all available data, whether to initiate Part 3 (Phase 3) of this study, where an additional 300 subjects will be randomly assigned in a 1:1 ratio to the 2 treatment arms. Patients are randomized to receive JNJ 63723283 (PD-1 antibody) administered in combination with daratumumab, compared with daratumumab alone. Daratumumab is dosed at 16 milligrams per kilo (mg/kg) weekly for 8 weeks, then once every other week for 16 weeks; then once every 4 weeks. JNJ 63723283 is dosed at 240 milligrams IV fixed dose during week 1 on cycle 1 (28 days) day 2, cycle 1 day 15, then every 2 weeks thereafter. The primary endpoints of the study are in Part 1: number of participants with adverse events (AE) including Dose-Limiting Toxicities (DLTs) during cycle 1. An adverse event is any untoward medical occurrence in participant who received study drug without regard to possibility of causal relationship. In Part 2: Overall Response Rate (ORR) as per International Myeloma Working Group (IMWG) criteria and in Part 3: Progression-Free Survival (PFS) which is the time from treatment start until the disease get worse.

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 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.¹ 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).^{1,2,3,4,5}

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. A comprehensive clinical development program for daratumumab is ongoing, including multiple Phase III studies in smoldering,

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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, 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/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.

¹ DARZALEX Prescribing information, May 2018. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761036s013lbl.pdf Last accessed May 2018

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.