

Genmab Announces Phase II Study of Daratumumab in Smoldering Multiple Myeloma

Company Announcement

- First study of daratumumab in smoldering multiple myeloma
- Study expected to start in 2015

Copenhagen, Denmark; November 24, 2014 – Genmab A/S (OMX: GEN) announced today that its collaboration partner, Janssen Biotech, Inc. (Janssen) plans to start a Phase II study of daratumumab in smoldering multiple myeloma. The study (SMM2001) will evaluate three different dose schedules of daratumumab for the treatment of smoldering multiple myeloma. The study is expected to start enrolling patients in 2015.

“We are pleased to announce this study, which illustrates that the development plan for daratumumab encompasses all stages of multiple myeloma. Smoldering multiple myeloma is a challenging indication, as physicians will evaluate treating patients at an early stage of the disease, with the intent to extend the period before the disease transitions to symptomatic multiple myeloma,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the SMM2001 study

This Phase II study will be a randomized, open-label, multicenter study and will enroll approximately 120 patients with high risk smoldering multiple myeloma. Patients will be randomized to receive one of three dose schedules of daratumumab. The study will be conducted by Janssen Research & Development LLC.

About daratumumab

Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA 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 (IMiD) or who are double refractory to a PI and an IMiD. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

About Genmab A/S

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company currently has one marketed antibody, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and daratumumab in late stage clinical development for multiple myeloma. Additionally Genmab has a clinical pipeline with both late and early stage programs, and an innovative pre-clinical 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. Genmab's deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com

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