



Genmab Announces New Study of Daratumumab in Double Refractory Multiple Myeloma

Company Announcement

- After initial data read-out in Part 1, study may possibly be expanded and continued in Part 2 for use as a potential registration study
- Patient recruitment expected to start soon

Copenhagen, Denmark; September 10, 2013 – Genmab A/S (OMX: GEN) announced today that its partner, Janssen Biotech, Inc. (“Janssen”) will start a new Phase II study of daratumumab in multiple myeloma. The Phase II study is designed in 2 parts in multiple myeloma patients who have received at least three different lines of therapy including both a proteasome inhibitor and an immunomodulatory agent (IMiD) or who are double refractory to a proteasome inhibitor and an IMiD. This is the same indication for which daratumumab was granted Breakthrough Therapy Designation from the FDA in May 2013.

“We continue to be excited by the prospects for daratumumab, which has the potential to offer a significant therapeutic alternative for multiple myeloma patients who desperately seek new treatment options,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “We look forward to the initiation of this trial with daratumumab in multiple myeloma patients, and we believe this study has the potential to be used for registration in the United States.”

About the Study

This two-part study will enroll up to a maximum of 110 patients who have received at least three prior lines of therapy, including both a proteasome inhibitor and an IMiD or who are double refractory to a proteasome inhibitor and an IMiD. Examples of proteasome inhibitors are bortezomib or carfilzomib and examples of IMiD agents are pomalidomide or lenalidomide. Part 1 will define an optimal daratumumab regimen going forward, while part 2 is an expansion based on the optimal regimen determined in Part 1. The primary objective of the study is to define the optimal dose and dosing schedule, to determine the efficacy of two treatment regimens of daratumumab as measured by overall response rate, and to further characterize the safety of daratumumab as a single agent.

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 could 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. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop 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's first marketed antibody, ofatumumab (Arzerra®), was approved to treat chronic lymphocytic leukemia in patients who are refractory to fludarabine and alemtuzumab after less than eight years in development. Genmab's validated and next generation antibody technologies are expected to provide a steady stream of future product candidates. Partnering of 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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