Genmab Announces Start of Rolling Submission of Biologics License Application for Daratumumab for Double Refractory Multiple Myeloma to the FDA

Company Announcement

- **Janssen Biotech, Inc. initiates rolling submission of BLA to U.S. FDA for daratumumab in double refractory multiple myeloma**
- **Submission based on data from Phase II study (Sirius MMY2002)**

Copenhagen, Denmark; June 5, 2015 – Genmab A/S (OMX: GEN) announced today its licensing partner Janssen Biotech, Inc. has initiated a rolling submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for daratumumab. The submission is for daratumumab as a treatment for patients with multiple myeloma 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. A rolling submission allows completed portions of the application to be submitted to the FDA on an ongoing basis. The FDA grants this type of review if the agency determines after a preliminary evaluation of clinical data that the breakthrough therapy may be effective and therefore, will consider reviewing portions of an application before the submission is complete. In August 2012, Genmab and Janssen Biotech, Inc. entered an agreement which granted Janssen a worldwide exclusive license to develop, manufacture and commercialize daratumumab. Janssen is currently the sponsor of all but one study globally.

The submission includes data from the Phase II study (Sirius MMY2002) of daratumumab in multiple myeloma 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. However, safety and efficacy data from the Phase I/II study (GEN501) and safety data from three other studies, have also been included in the BLA submission. Daratumumab received a Breakthrough Therapy Designation (BTD) for this indication from the FDA in May 2013.

“Daratumumab is a highly innovative antibody that holds promise for patients with multiple myeloma, a disease for which there is currently no cure. Today, patients that are double refractory have run out of treatment options and we are very pleased that daratumumab offers the potential to help this group of patients. The initiation of this rolling BLA submission is a landmark in the development of daratumumab and we are working together with Janssen to bring this new treatment option to patients as quickly as we can,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About multiple myeloma
Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells.[1] Multiple myeloma is the third most common blood cancer in the United States (U.S.), following only leukemia and lymphoma.[2] Approximately 26,850 new patients will be diagnosed with multiple myeloma and approximately 11,240 people will die from the disease in the U.S. in 2015.[3] Globally, it is estimated that 114,251 people will be diagnosed and 80,019 will die from the disease.[4] While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms which can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[5]

About daratumumab
Daratumumab is an investigational human IgG1k monoclonal antibody (mAb) that binds with high affinity to the transmembrane ectoenzyme, CD38, on the surface of multiple myeloma cells. It induces rapid tumor cell death through diverse mechanisms of action. Five Phase III clinical studies with daratumumab in relapsed and frontline settings are currently ongoing. Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as

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smoldering myeloma and non-Hodgkin's lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA.

About Genmab
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 clinical development for multiple myeloma and non-Hodgkin's lymphoma, in addition to other clinical 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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References
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[3] American Cancer Society. "What are the key statistics about multiple myeloma?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-key-statistics. Accessed February 5, 2015.
[4] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide. Available at http://globocan.iarc.fr/Pages/fact_sheets_population.aspx. Accessed May 19, 2015.
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