Genmab Announces European Regulatory Submission for Daratumumab in Double Refractory Multiple Myeloma

Company Announcement

- **MAA submitted to EMA by Janssen for daratumumab in multiple myeloma**
- **Submission mainly based on data from Phase II study (Sirius MMY2002)**

Copenhagen, Denmark; September 9, 2015 – Genmab A/S (OMX: GEN) announced today that Janssen-Cilag International NV (Janssen) has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) 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 (PI) and an immunomodulatory agent (IMiD) or who are double refractory to a PI and an IMiD. The submission triggers a milestone payment of USD 10 million to Genmab from Janssen. The milestone was included in Genmab's financial guidance for 2015. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

This submission in Europe follows the completion of the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in July this year. Both regulatory submissions include 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 PI and an IMiD, or who are double refractory to a PI 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 submission.

"The submission of the European regulatory application for daratumumab is another significant milestone in the development of daratumumab. We have seen very promising clinical data and believe daratumumab could provide an important new treatment alternative for multiple myeloma patients if approved," 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 U.S., after 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 124,225 people will be diagnosed and 87,084 will die from the disease in 2015.[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] Patients who relapse after treatment with standard therapies, including PIs or IMiDs, have poor prognoses and few treatment options.[6]

About daratumumab
Daratumumab is an investigational 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. It induces rapid tumor cell death through multiple immune-mediated mechanisms[7], including complement-dependent cytotoxicity[7], antibody-dependent cellular phagocytosis[8] and antibody-dependent cellular cytotoxicity[7], as well as via induction of apoptosis[9]. 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 smoldering myeloma and non-Hodgkin 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 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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