Genmab Announces Completion of Rolling Submission of Biologics License Application for Daratumumab in Multiple Myeloma and Achievement of a USD 15 Million Milestone

Company Announcement

- **Submission of rolling BLA to US FDA for daratumumab in multiple myeloma completed by Janssen Biotech, Inc.**
- **Completion of submission triggers USD 15 million milestone payment to Genmab**

Copenhagen, Denmark; July 9, 2015 – Genmab A/S (OMX: GEN) announced its licensing partner Janssen Biotech, Inc. has completed the rolling submission of the 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 prior 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. In May, 2013, daratumumab was granted a Breakthrough Therapy Designation (BTD) in this population. The completion of the submission triggers a milestone payment of USD 15 million to Genmab from Janssen. The milestone was included in Genmab's financial guidance for 2015, which was updated on May 20, 2015. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

A request for Priority Review has been submitted by Janssen with this BLA. The FDA will inform Janssen whether a Priority Review has been granted by calendar day 60 of their review starting today. If the FDA grants Priority Review the review period may not exceed 6 months from that date.

If daratumumab receives FDA approval, Genmab will receive a milestone payment from Janssen of USD 45 million associated with the first commercial sale of the product in the United States. However, it is not possible to precisely predict the timing of a potential marketing approval and first commercial sale; therefore, this milestone has not been included in the 2015 financial guidance at this time.

"The rapid completion of the BLA submission brings us a significant step closer to the potential regulatory approval of daratumumab," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "Daratumumab received Breakthrough Therapy Designation from the FDA for this indication for multiple myeloma patients who have no other treatment options available, and we are proud that our partner Janssen has completed the submission in record time."

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 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 BLA submission.

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

Genmab Announces Completion of Rolling Submission of Biologics License Application for Daratumumab in Multiple Myeloma and Achievement of a USD 15 Million Milestone

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 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.

Contact:
Rachel Curtis Gravesen, Senior Vice President, Investor Relations & Communications
T: +45 33 44 77 20; M: +45 25 12 62 60; E: r.gravesen@genmab.com

This Company Announcement contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with pre-clinical and clinical development of products, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. For a further discussion of these risks, please refer to the risk management sections in Genmab's most recent financial reports, which are available on www.genmab.com. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements in relation to actual results, unless required by law.

References
[1] American Cancer Society. "Multiple Myeloma Overview" http://www.cancer.net/cancer-types/multiple-myeloma/overview. Accessed November 24, 2014.
[2] National Cancer Institute. "A Snapshot of Myeloma." Available at www.cancer.gov/research/progress/snapshots/myeloma. Accessed May 19, 2015.
[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.
[5] American Cancer Society. "How is Multiple Myeloma Diagnosed?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed November 24, 2014.