U.S. FDA Grants Priority Review for Daratumumab for Double Refractory Multiple Myeloma

Company Announcement

- **U.S. FDA grants Priority Review to daratumumab**
- **PDUFA target date has been set to March 9, 2016**

Copenhagen, Denmark; September 4, 2015 – Genmab A/S (OMX: GEN) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review to the Biologics License Application (BLA) for daratumumab. The BLA 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 BLA submission was started by Genmab's licensing partner, Janssen Biotech, Inc. in June and was completed on July 9, 2015. In August 2012, Genmab granted Janssen an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

Priority Review is an FDA designation for drugs that treat a serious condition and may provide a significant improvement in safety or efficacy. The FDA aims to complete its review of the daratumumab BLA within six months and has assigned a Prescription Drug User Fee Act (PDUFA) target date of March 9, 2016.

"We are pleased that the FDA has granted Priority Review for daratumumab in double refractory multiple myeloma. If approved, daratumumab has the potential to make a real difference in the lives of people who have run out of other treatment options for multiple myeloma," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The BLA 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. Daratumumab received a Breakthrough Therapy Designation for this indication from the FDA in May 2013.

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.

U.S. FDA Grants Priority Review for Daratumumab for Double Refractory Multiple Myeloma

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.

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." Available at http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Accessed August 2015.
[2] National Cancer Institute. "A Snapshot of Myeloma." Available at www.cancer.gov/research/progress/snapshots/myeloma. Accessed August 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 August 2015.
[4] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide. Available at: http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=17270&Text-c=Multiple+myeloma&pYear=3&type=0&window=1&submit=%C2%A0Execute. Accessed August 2015.
[5] American Cancer Society. "How is Multiple Myeloma Diagnosed?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed August 2015.
[6] Kumar, SK et al. *Leukemia*. 2012 Jan;26(1):149-57.
[7] Michael de Weers et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematological Tumors. *The Journal of Immunology*. February 1, 2011vol. 186 no. 3 1840-1848.
[8] Yulian Khagi and Tomer M Mark. Potential role of daratumumab in the treatment of multiple myeloma. Onco Targets Ther. 2014; 7: 1095–1100.
[9] Jing Yang and Qing Yi. Therapeutic monoclonal antibodies for multiple myeloma: an update and future perspectives. Am J Blood Res. 2011; 1(1): 22–33.