

U.S. FDA Grants Priority Review for Daratumumab in Relapsed Multiple Myeloma

Company Announcement

- U.S. FDA grants Priority Review to daratumumab in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for relapsed multiple myeloma – February 17, 2017 PDUFA date
- U.S. FDA grants Standard Review to daratumumab in combination with pomalidomide and dexamethasone for relapsed or refractory multiple myeloma – June 17, 2017 PDUFA date

Copenhagen, Denmark; October 7, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review to the supplemental Biologics License Application (sBLA) for the use of daratumumab (DARZALEX®) in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. The sBLA was submitted by Genmab's licensing partner, Janssen Biotech, Inc. in August 2016. 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 has assigned a Prescription Drug User Fee Act (PDUFA) target date of February 17, 2017 to take a decision on daratumumab in this indication. In addition, the FDA has granted a Standard Review period for the use of daratumumab in combination with pomalidomide and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received at least two prior therapies, with a proteasome inhibitor and an immunomodulatory agent. The PDUFA date for the combination of daratumumab with pomalidomide/dexamethasone is June 17, 2017.

The FDA granted a Breakthrough Therapy Designation for daratumumab in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy in July 2016.

“People suffering from multiple myeloma always ultimately relapse after receiving treatment with the therapies available today. The application for daratumumab in combination with current backbone therapies for patients who have already received at least one type of treatment is a key step towards trying to bring new treatment options to patients with multiple myeloma,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The sBLA submission included data from two Phase III studies: the CASTOR study of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone alone in patients with relapsed or refractory multiple myeloma, and the POLLUX study of daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone in patients with relapsed or refractory multiple myeloma. The submission also included data from the Phase I study of daratumumab in combination with pomalidomide and dexamethasone in relapsed or refractory multiple myeloma.

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 30,330 new patients are expected to be diagnosed with multiple myeloma and approximately 12,650 people are expected to die from the disease in the U.S. in 2016.³ Globally, it was estimated that 124,225 people would be diagnosed and 87,084 would 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,

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kidney problems or infections.⁵ Patients who relapse after treatment with standard therapies, including proteasome inhibitors or immunomodulatory agents, have poor prognoses and few treatment options.⁶

About DARZALEX® (daratumumab)

DARZALEX® (daratumumab) injection for intravenous infusion is indicated in the United States for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.⁷ DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (FDA) approval to treat multiple myeloma. DARZALEX is indicated in Europe for use as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. For more information, visit www.DARZALEX.com.

Daratumumab is a 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 is believed to induce rapid tumor cell death through programmed cell death, or apoptosis,^{7,8} and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,^{7,8} antibody-dependent cellular phagocytosis^{9,10} and antibody-dependent cellular cytotoxicity.^{7,8} In addition, daratumumab therapy results in a reduction of immune-suppressive myeloid derived suppressor cells (MDSCs) and subsets of regulatory T cells (Tregs) and B cells (Bregs), all of which express CD38. These reductions in MDSCs, Tregs and Bregs were accompanied by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow.^{7,11}

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. Five Phase III clinical studies with daratumumab in relapsed and frontline settings are currently ongoing, and 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, non-Hodgkin's lymphoma and a solid tumor.

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 has two approved antibodies, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and DARZALEX® (daratumumab) for the treatment of heavily pretreated or double refractory multiple myeloma. Daratumumab is in clinical development for additional multiple myeloma indications and for non-Hodgkin's lymphoma. Genmab also has a broad clinical and pre-clinical product 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. The company intends to leverage these technologies to create opportunities for full or co-ownership of future products. Genmab 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

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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.

Genmab A/S and its subsidiaries own the following trademarks: Genmab[®]; the Y-shaped Genmab logo[®]; Genmab in combination with the Y-shaped Genmab logo[™]; the DuoBody logo[®]; the HexaBody logo[™]; HuMax[®]; HuMax-CD20[®]; DuoBody[®]; HexaBody[®] and UniBody[®]. Arzerra[®] is a trademark of Novartis AG or its affiliates. DARZALEX[®] is a trademark of Janssen Biotech, Inc.

¹ American Cancer Society. "Multiple Myeloma Overview." Available at <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Accessed June 2016.

² National Cancer Institute. "A Snapshot of Myeloma." Available at www.cancer.gov/research/progress/snapshots/myeloma. Accessed June 2016.

³ American Cancer Society. "What are the key statistics about multiple myeloma?"

<http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-key-statistics>. Accessed June 2016.

⁴ GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of New Cancers in 2015. 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 June 2016.

⁵ American Cancer Society. "How is Multiple Myeloma Diagnosed?"

<http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis>. Accessed June 2016.

⁶ Kumar, SK et al. Risk of progression and survival in multiple myeloma relapsing after last therapy with IMiDs and bortezomib: a multicenter international myeloma working group study. *Leukemia*. 2012; 26:149-57.

⁷ DARZALEX US Prescribing Information, November 2015.

⁸ De Weers, M et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematological Tumors. *The Journal of Immunology*. 2011; 186: 1840-1848.

⁹ Overdijk, MB, et al. Antibody-mediated phagocytosis contributes to the anti-tumor activity of the therapeutic antibody daratumumab in lymphoma and multiple myeloma. *MAbs*. 2015; 7: 311-21.

¹⁰ Khagi, Y and Mark, TM. Potential role of daratumumab in the treatment of multiple myeloma. *Onco Targets Ther*. 2014; 7: 1095–1100.

¹¹ Krejcik, MD et al. Daratumumab Depletes CD38+ Immune-regulatory Cells, Promotes T-cell Expansion, and Skews T-cell Repertoire in Multiple Myeloma. *Blood*. 2016; 128: 384-94.