

CHMP Grants Accelerated Assessment for Daratumumab for Double Refractory Multiple Myeloma

Company Announcement

- CHMP grants accelerated assessment to daratumumab
- MAA submitted September 9 by Janssen based on data from Phase II study (Sirius MMY2002)

Copenhagen, Denmark; September 25, 2015 – Genmab A/S (OMX: GEN) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted accelerated assessment to the Marketing Authorization Application (MAA) for daratumumab. The MAA is for daratumumab as a treatment for patients with relapsed and refractory multiple myeloma. The MAA was submitted to the EMA on September 9, 2015 by Janssen-Cilag International NV. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

The CHMP grants accelerated assessment when a medicinal product is expected to be of major public health interest particularly from the point of view of therapeutic innovation.

“Patients with multiple myeloma, particularly those who have exhausted all approved treatment options, are waiting for new medicines to treat this incurable disease. An accelerated approval optimizes the potential for daratumumab to provide a new therapy for this patient group more rapidly than under a standard review time,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The MAA 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 (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and an IMiD. 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. A regulatory application for daratumumab has also been submitted to the U.S. Food and Drug Administration and has been granted Priority Review with a PDUFA date of March 9, 2016.

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 mechanisms⁷, including complement-dependent cytotoxicity⁷, antibody-dependent cellular phagocytosis⁸ and antibody-dependent cellular cytotoxicity⁷, as well as via induction of apoptosis⁹. 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.

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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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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 Pharma AG.

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 Michel 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, 2011 vol. 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.