

U.S. FDA Grants Priority Review for Ofatumumab as Maintenance Therapy for Relapsed CLL

Company Announcement

- U.S. FDA grants Priority Review to sBLA for ofatumumab as maintenance therapy in relapsed CLL
- PDUFA target date has been set to January 21, 2016

Copenhagen, Denmark; September 19, 2015 – Genmab A/S (OMX: GEN) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review to the supplemental Biologics License Application (sBLA) for ofatumumab (Arzerra®) as maintenance therapy of patients with relapsed chronic lymphocytic leukemia (CLL). The application was submitted to the FDA by Novartis under our ofatumumab collaboration in July 2015.

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 ofatumumab sBLA within the time set by the Prescription Drug User Fee Act (PDUFA) and has given a target date for completion of their review of January 21, 2016.

“We are very pleased that the FDA has granted Priority Review for ofatumumab, which means ofatumumab could potentially be available as a maintenance therapy for patients suffering from relapsed CLL relatively soon,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “We look forward to receiving FDA’s feedback on the application.”

The application is based on interim results from a Phase III study, PROLONG (OMB112517) which evaluated ofatumumab maintenance therapy versus no further treatment in patients with a complete or partial response after second or third line treatment for CLL. Results from this trial were presented at the 2014 American Society of Hematology Annual Meeting.

About CLL

CLL, the most commonly diagnosed adult leukemia in Western countries, accounts for approximately 1 in 4 cases of leukemia^{1,2}. Most CLL patients experience disease progression despite initial response to therapy and may require additional treatment³.

About Ofatumumab (Arzerra®)

Ofatumumab is a human monoclonal antibody that is designed to target the CD20 molecule found on the surface of chronic lymphocytic leukemia (CLL) cells and normal B lymphocytes.

In the United States, Arzerra is approved for use in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate. In the European Union, Arzerra is approved for use in combination with chlorambucil or bendamustine for the treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy. In more than 50 countries worldwide, Arzerra is also indicated as monotherapy for the treatment of patients with CLL who are refractory after prior treatment with fludarabine and alemtuzumab.

Arzerra is not approved anywhere in the world as maintenance therapy for relapsed chronic lymphocytic leukemia.

[Please see full Prescribing Information, including Boxed WARNING for Arzerra \(ofatumumab\).](#)

Arzerra is marketed under a collaboration agreement between Genmab and Novartis.

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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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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.

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.

References

1. Chronic Lymphocytic Leukemia. Leukemia & Lymphoma Society Website. <http://www.lls.org/#/diseaseinformation/leukemia/chroniclymphocyticleukemia/>. Accessed April 8, 2014.
2. What are the key statistics for chronic lymphocytic leukemia? American Cancer Society Website. <http://www.cancer.org/cancer/leukemia-chroniclymphocyticcll/detailedguide/leukemia-chronic-lymphocytic-key-statistics>. Published February 26, 2015. Accessed April 8, 2015.
3. Veliz M, Pinilla-Ibarz J. Treatment of relapsed or refractory chronic lymphocytic leukemia. *Cancer Control*. 2012; 1:37-53.