Genmab Announces European Regulatory Submission for Ofatumumab as Maintenance Therapy for Relapsed CLL

Company Announcement

- **Application to broaden label for ofatumumab as maintenance therapy in relapsed CLL submitted to EMA by Novartis**
- **Submission based on data from interim results of Phase III PROLONG study**

Copenhagen, Denmark; July 7, 2015 – Genmab A/S (OMX: GEN) announced today that a variation to the Marketing Authorization has been submitted to the European Medicines Agency (EMA) for the use of ofatumumab (Arzerra®) as maintenance therapy of patients with relapsed chronic lymphocytic leukemia (CLL). The application was submitted by Novartis under our ofatumumab collaboration.

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.

"The PROLONG study showed the potential of using ofatumumab as an ongoing maintenance therapy for patients with relapsed CLL. We are pleased that Novartis has taken the next step with ofatumumab in this setting by submitting a regulatory application to the EMA," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

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 treatment[3].

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 co-development and collaboration agreement between Genmab and Novartis, as successor in interest to GSK.

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

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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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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.