European Commission Grants Marketing Authorization for Arzerra® (ofatumumab) in combination with Fludarabine and Cyclophosphamide in Relapsed CLL

Media Release

- **Arzerra approved in EU for use in combination with fludarabine and cyclophosphamide in relapsed CLL**
- **Approval follows November CHMP recommendation**
- **Approval based on data from Phase III COMPLEMENT 2 study**

Copenhagen, Denmark; December 12, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the European Commission (EC) has granted a marketing authorization for the use of ofatumumab (Arzerra®) in combination with fludarabine and cyclophosphamide (FC) for the treatment of adult patients with relapsed chronic lymphocytic leukemia (CLL) in the European Union. The variation to the Marketing Authorization for this indication was submitted to the European Medicines Agency (EMA) in March 2016 by Novartis under the ofatumumab collaboration between Novartis and Genmab. Subsequently, on November 10, the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending that Arzerra be approved in this indication.

"We welcome this decision by the European Commission to expand the use of Arzerra, as this further broadens the treatment options for CLL patients in Europe," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The EC's approval was based on results from the Phase III COMPLEMENT 2 study that evaluated ofatumumab in combination with FC versus FC alone in patients with relapsed CLL. Top-line results from COMPLEMENT 2 were reported in April 2015.

About CLL
CLL is the most commonly diagnosed adult leukemia in Western countries, and accounts for approximately 1 in 4 cases of leukemia.[1] Most CLL patients experience disease progression despite initial response to therapy and may require additional treatment.[2]

About COMPLEMENT 2
COMPLEMENT 2 (NCT00824265) is an open-label, two-arm, randomized, Phase III study, which included 365 patients in 18 countries with relapsed CLL. Patients in the study were randomized 1:1 to treatment with up to six cycles of ofatumumab in combination with fludarabine and cyclophosphamide (FC) or up to six cycles with fludarabine and cyclophosphamide alone.

The primary endpoint of the study was progression free survival (PFS), which was assessed by an Independent Review Committee (IRC) according to the International Workshop for Chronic Lymphocytic Leukaemia (iwCLL) updated 2008 National Cancer Institute-sponsored Working Group (NCIWG) guidelines.[3] The study met the primary endpoint with a median progression free survival in patients receiving ofatumumab in combination with FC of 28.9 months, compared to 18.8 months in patients receiving FC alone (HR =0.67, p=0.0032). Secondary endpoints included overall response rate, overall survival, patient reported outcomes, time to response, duration of response, time to progression, time to next therapy, safety assessments and quality of life. The safety profile observed in this study was consistent with other trials of ofatumumab and no new safety signals were observed.

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.

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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, for use in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL, and for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL. 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.

Under the collaboration with Novartis, a subcutaneous formulation of ofatumumab is in Phase III development for relapsing multiple sclerosis.

Please see full Prescribing Information, including Boxed WARNING for Arzerra (ofatumumab).

Arzerra is marketed under a collaboration agreement between Genmab and Novartis. Novartis has rights to develop ofatumumab in autoimmune indications, including multiple sclerosis.

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, DARZALEX® (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications, non-Hodgkin's lymphoma and solid tumors. A subcutaneous formulation of ofatumumab is in development for relapsing multiple sclerosis. 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.

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This Media Release 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 Media Release nor to confirm such statements in relation to actual results, unless required by law.

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References

[1] GlobalData. EpiCast Report: Chronic Lymphocytic Leukemia Epidemiology Forecast to 2023. Published May 2014.
[2] Veliz M, Pinilla-Ibarz J. Treatment of relapsed or refractory chronic lymphocytic leukemia. Cancer Control. 2012; 1:37-53.
[3] Hallek M, Cheson BD, Catovsky D, et al. Guidelines for the diagnosis and treatment of chronic lymphocytic leukemia: a report from the International Workshop on Chronic Lymphocytic Leukemia updating the National Cancer Institute-Working Group 1996 guidelines. Blood 2008; 111: 5446-56.