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Genmab Announces Topline Results in Phase III study of Arzerra® in Indolent Non-Hodgkin's Lymphoma

Company Announcement

- ▮ **Topline results from Phase III study in iNHL did not meet primary endpoint of improved progression-free survival**

Copenhagen, Denmark; May 24, 2018 — Genmab A/S (Nasdaq Copenhagen: GEN) announced today that topline results from the Phase III study of Arzerra® (ofatumumab) plus bendamustine did not meet the primary endpoint of improved progression-free survival (PFS) in patients with indolent B-cell non-Hodgkin's lymphoma (iNHL) who were unresponsive to rituximab or a rituximab-containing regimen, compared to those given bendamustine alone. The safety profile observed in this study was consistent with that observed in other trials of ofatumumab and no new safety signals were observed.

"We are disappointed that the ofatumumab treatment regimen did not meet the primary endpoint in this trial. The completion of this Phase III study, which began in 2010, would not have been possible without the generous participation of the patients and their families, and we are most grateful for this. The full data will be submitted for publication at a future medical conference and we hope that these will provide a better understanding of this result," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The results from this Phase III study do not impact any other ongoing studies with ofatumumab.

About the study (COMPLEMENT A+B)

The study is an open-label, two-arm, randomized, Phase III study that included 346 patients with indolent B-cell non-Hodgkin's lymphoma who were unresponsive to rituximab or a rituximab-containing regimen. Patients in the study were randomized 1:1 to treatment with up to eight cycles of bendamustine given in combination with 12 doses of ofatumumab (1,000 mg) or up to eight cycles with bendamustine alone. The primary endpoint of the study was PFS.

Ofatumumab is not approved for the treatment of indolent non-Hodgkin's Lymphoma.

About Ofatumumab (Arzerra®)

Ofatumumab is a human monoclonal antibody that is designed to target the CD20 molecule found on the surface of normal B lymphocytes and on B cell malignancies (including chronic lymphocytic leukemia and non-Hodgkin's lymphomas).

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 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 and in combination with fludarabine and cyclophosphamide for adult patients with relapsed CLL. In more than 60 countries worldwide, including the United States and EU member countries, Arzerra is also indicated as monotherapy for the treatment of patients with CLL who are refractory after prior treatment with fludarabine and alemtuzumab. On January 22, 2018, it was announced that Novartis intends to transition Arzerra for the treatment of CLL indications from commercial availability to limited availability via compassionate use programs in non-U.S. markets.

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

Arzerra is marketed under a collaboration agreement between Genmab and Novartis. A subcutaneous formulation of ofatumumab is also being investigated in two Phase III clinical studies in relapsing 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, other blood cancers, 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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