

Genmab Announces Ofatumumab Phase III Study in Follicular Lymphoma to be Stopped Following Planned Interim Analysis

Company Announcement

- Phase III study of ofatumumab in follicular lymphoma will be stopped early
- Planned interim analysis by an Independent Data Monitoring Committee showed that the study was unlikely to show superiority of ofatumumab if completed
- No new safety signals for ofatumumab were identified

Copenhagen, Denmark; November 23, 2015 – Genmab A/S (OMX: GEN) announced today that the Phase III study of single agent ofatumumab compared to single agent rituximab in patients with follicular non-Hodgkin's lymphoma (NHL) that has relapsed at least 6 months after completion of treatment with a rituximab-containing regimen will be stopped early. The decision to stop the study was made after a planned interim analysis performed by an Independent Data Monitoring Committee (IDMC) showed that it was unlikely that ofatumumab would show superiority if the trial was to be completed as planned.

"The outcome of the interim analysis in this study is disappointing as we had hoped to see superiority of ofatumumab. The data from the study will now be prepared so that it can be presented at a future scientific conference," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Today's news does not impact any other ongoing studies with ofatumumab.

About the study

This Phase III study aimed to randomize up to 516 patients to receive ofatumumab (1000 mg) or rituximab (375 mg/m²) by intravenous infusion for four weekly doses. Patients who had stable or responsive disease then received single infusions of ofatumumab or rituximab every two months for four additional doses for a total of eight doses over nine months. The primary endpoint of the study was progression free survival.

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 treatment for relapsed follicular NHL.

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

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

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, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and DARZALEX™ (daratumumab) for the treatment of heavily

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pretreated or double refractory multiple myeloma. Daratumumab is in clinical development for additional multiple myeloma indications and for non-Hodgkin's lymphoma. 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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