GENMAB PROVIDES UPDATE ON OFATUMUMAB PHASE III HEAD TO HEAD STUDY IN DLBCL

- Protocol amendment submitted to regulatory authorities
- Chemotherapy regimen to be focused
- Estimate for primary data readout moved forward

Copenhagen, Denmark; March 19, 2012 – Genmab A/S (OMX: GEN) announced today the submission of a protocol amendment for the ofatumumab Phase III head-to-head study in diffuse large B-cell lymphoma (DLBCL) to regulatory authorities. According to the amended protocol all patients recruited in the study which investigates ofatumumab plus chemotherapy versus rituximab plus chemotherapy in relapsed or refractory DLBCL, will receive the same chemotherapy regimen (DHAP). This change will revise underlying timing assumptions in the study and could bring forward the primary endpoint analysis to early 2014.

“We look forward to discussing the changes with regulators ahead of potential regulatory filings for ofatumumab in relapsed or refractory DLBCL that could take place as early as the end of 2014,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the study
The study now includes 410 patients who are refractory to or have relapsed following first line treatment with rituximab in combination with a chemotherapy regimen containing anthracycline and are eligible for autologous stem cell transplant (ASCT). Patients in the study will be randomized to receive three cycles of either ofatumumab or rituximab in addition to DHAP chemotherapy. After the third treatment cycle patients who obtain a complete or partial response will receive high dose chemotherapy followed by ASCT. The primary endpoint of the study is progression free survival.

About ofatumumab
Ofatumumab is a human monoclonal antibody which targets an epitope in the CD20 molecule encompassing parts of the small and large extracellular loops (Teeling et al 2006). Ofatumumab is not approved in any country for treatment of relapsed or refractory DLBCL. Ofatumumab is being developed under a co-development and commercialization agreement between Genmab and GlaxoSmithKline.

In the United States and Europe, ofatumumab is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab. The effectiveness of ofatumumab is based on the demonstration of durable objective responses. No data demonstrate an improvement in disease-related symptoms or increased survival. Ofatumumab can cause serious infusion reactions, prolonged and severe cytopenias, Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, and Hepatitis B infection and reactivation.

About Genmab A/S
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’s first marketed antibody, ofatumumab (Arzerra®), was approved to treat chronic lymphocytic leukemia in patients who are refractory to fludarabine and alemtuzumab after less than eight years in development. Genmab’s validated and next generation antibody technologies are expected to provide a steady stream of future product candidates. Partnering of 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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