



## **GENMAB ANNOUNCES DETAILS OF PLANNED OFATUMUMAB PHASE II STUDY IN MULTIPLE SCLEROSIS**

*Summary: Genmab has announced details of a planned Phase II study of ofatumumab to treat relapsing remitting multiple sclerosis.*

**Copenhagen, Denmark; December 13, 2007** – Genmab A/S (OMX: GEN) announced today details of a planned Phase II study of ofatumumab (HuMax-CD20<sup>®</sup>) for the treatment of relapsing remitting multiple sclerosis (RRMS). Approximately 324 patients will be enrolled in the study which will be conducted under Genmab’s collaboration with GlaxoSmithKline (GSK). The study is expected to begin in the first quarter of 2008.

Ofatumumab is an investigational, fully human, next generation monoclonal antibody that targets a unique epitope of the CD20 receptor on the surface of B-cells. Other anti-CD20 antibodies currently available or in development bind to a different epitope on the CD20 receptor. Ofatumumab is being developed under a co-development and commercialization agreement between Genmab and GlaxoSmithKline.

“Multiple sclerosis is a debilitating disease for which there are currently few treatments,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab. “We hope our fully human antibody, ofatumumab, may offer another potential treatment option for patients suffering from this incapacitating disease.”

### **About the trial**

The double blind randomized trial will consist of two parts. Part A will include approximately 36 patients in one of three increasing dose cohorts (100 mg, 300 mg or 700 mg of ofatumumab) randomized to receive ofatumumab or placebo. An independent data monitoring committee (IDMC) will evaluate the safety of each sequential cohort prior to progression to the next cohort. When all patients in Part A have had their week 4 MRI scan, the IDMC will evaluate the data before Part B of the study begins.

Part B will consist of a 48 week treatment period of approximately 288 patients. Patients will be randomized to treatment with 100 mg, 300 mg, or 700 mg of ofatumumab or placebo. After week 24, patients on an active dose will receive re-treatment with the same dose of ofatumumab or placebo. Patients on placebo will receive ofatumumab at the highest tolerated dose from Part A.

The objective of the study is to determine the safety and tolerability of three doses of ofatumumab and the dose response of ofatumumab on disease activity on MRI in patients with

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RRMS. The primary endpoints are safety and cumulative number of new Gd-enhanced lesions from week 8 to week 24.

## About Relapsing Remitting Multiple Sclerosis

Multiple Sclerosis (MS) is an inflammatory disease of the central nervous system. MS is twice as common in females as in males, occurs with a peak incidence at the age of 35 years and incidence varies widely in different populations and ethnic groups. The etiology of MS remains unknown, but the geographic variation points towards possible environmental and genetic factors. The most common form of MS is relapsing remitting MS characterized by unpredictable recurrent attacks where the symptoms usually evolve over days and are followed by either complete, partial or no neurological recovery. No progression of neurological impairment is experienced between attacks.

## About Genmab A/S

Genmab is a leading international biotechnology company focused on developing fully human antibody therapeutics for unmet medical needs. Using unique, cutting-edge antibody technology, Genmab's world class discovery and development teams have created and developed an extensive pipeline of products for potential treatment of a variety of diseases including cancer and autoimmune disorders. As Genmab advances towards a commercial future, we remain committed to our primary goal of improving the lives of patients who are in urgent need of new treatment options. For more information on Genmab's products and technology, visit [www.genmab.com](http://www.genmab.com).

*This press 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 product discovery and development, 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. Genmab is not under an obligation to up-date statements regarding the future following the publication of this release; nor to confirm such statements in relation to actual results, unless this is required by law.*

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