



## **GENMAB ANNOUNCES UPCOMING OFATUMUMAB STUDIES**

Front Line CLL, NHL and CLL Retreatment and Japanese Development Studies Planned

*Summary: Genmab has announced plans to begin four studies of ofatumumab in chronic lymphocytic leukemia and non-Hodgkin's lymphoma.*

**Copenhagen, Denmark; August 25, 2008** – Genmab A/S (OMX: GEN) announced today plans to begin four studies of ofatumumab in chronic lymphocytic leukemia (CLL) and follicular non-Hodgkin's lymphoma (NHL) this year.

“Genmab and GSK have worked diligently to expand the ofatumumab development program to maximize the value of the antibody for patients and shareholders since our collaboration began,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab. “The new studies we are initiating this year will examine the potential of ofatumumab in Japan as well as a number of new treatment settings – retreatment, maintenance and front line with chlorambucil.”

### **Phase III CLL front line chlorambucil combination**

This open-label, parallel-arm study will include 444 patients with previously untreated CLL. Patients in the study will be randomized to receive ofatumumab in combination with chlorambucil or chlorambucil alone. Patients receiving ofatumumab in combination with chlorambucil will receive one infusion of ofatumumab at 300 mg, one infusion at 1000 mg a week later, followed by up to 11 monthly infusions at 1000 mg. Patients will be evaluated for disease status one month following last treatment then every 3 months for 5 years.

The primary objective of the study is to evaluate the progression free survival of ofatumumab in combination with chlorambucil therapy versus chlorambucil therapy alone for the treatment of front line CLL.

### **Phase II CLL ofatumumab retreatment and maintenance treatment study**

This study will examine the retreatment and maintenance treatment of refractory CLL patients who participated in the ongoing Phase III CLL study and had disease progression following at least an objective response or stable disease during a 24 week treatment period of ofatumumab. Eligible patients will receive one infusion of ofatumumab at 300 mg followed by 7 once weekly infusions at 2000 mg. Maintenance treatment will consist of 24 once monthly infusions of 2000 mg of ofatumumab. The primary objective of this study is to estimate the proportion of objective responses over 52 weeks.

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## **Phase II NHL ofatumumab retreatment and maintenance study**

This study will examine the retreatment and maintenance treatment of refractory follicular NHL patients who participated in the ongoing Phase III NHL study and had disease progression following at least 6 months objective response to or stable disease on ofatumumab. Eligible patients will receive one infusion of ofatumumab at 300 mg followed by 7 once weekly infusions at 1000 mg. Maintenance treatment will consist of one 1000 mg infusion every two months for two years. The primary objective of this study is to evaluate the safety of ofatumumab retreatment and maintenance treatment.

## **Phase I study in Japan**

This open-label study will include a maximum of 12 patients with relapsed/refractory follicular NHL and at least 1 CLL patient who will be divided into 2 cohorts of 3 or 6 patients each. Patients will receive one infusion of ofatumumab at 300 mg followed by seven weekly infusions of 500 or 1000 mg of ofatumumab. Safety at the 500 mg dose level of ofatumumab will be examined before progressing to the 1000 mg dose level. The primary objective of the study is to evaluate the safety and tolerability of ofatumumab in Japanese relapsed/refractory follicular NHL and CLL patients. The primary endpoint of the study is safety.

Ofatumumab is an investigational new generation human monoclonal antibody that targets a distinct, membrane proximal, small loop epitope (specific antibody binding site) of the CD20 molecule on B cells. Ofatumumab is being developed to treat chronic lymphocytic leukemia, follicular non-Hodgkin's lymphoma, diffuse large B-cell lymphoma, rheumatoid arthritis and relapsing remitting Multiple Sclerosis under a co-development and commercialization agreement between Genmab and GlaxoSmithKline. It is not yet approved in any country.

## **About Genmab A/S**

Genmab is a leading international biotechnology company focused on developing fully human antibody therapeutics for unmet medical needs. Using cutting-edge antibody technology, Genmab's world class discovery, development and manufacturing 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. For a further discussion of these risks, please refer to the section "Risk Management" in Genmab's Annual Report, which is available on [www.genmab.com](http://www.genmab.com). Genmab*

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