



## **GENMAB AND GLAXOSMITHKLINE ANNOUNCE POSITIVE TOP-LINE RESULTS IN OFATUMUMAB CHRONIC LYMPHOCYTIC LEUKEMIA PIVOTAL STUDY**

*Summary: Phase III pivotal study of ofatumumab in refractory CLL meets primary endpoint.*

**Copenhagen, Denmark; July 31, 2008** – Genmab A/S (OMX: GEN) and GlaxoSmithKline (LSE and NYSE: GSK) announced today positive top-line results from an interim analysis of the Phase III pivotal study evaluating ofatumumab (HuMax-CD20<sup>®</sup>) to treat two groups of chronic lymphocytic leukemia (CLL) patients with high unmet medical need. At the interim analysis, the study met the primary endpoint in both populations and the results from the secondary endpoints also support the primary endpoint.

The activity of ofatumumab was evaluated in 154 patients in this interim analysis of whom 138 patients with refractory CLL were evaluable. About half of the patients (59) in the study were refractory to both fludarabine and alemtuzumab. The analysis also included a second group (79) who were refractory to fludarabine and considered inappropriate candidates for alemtuzumab due to bulky tumor in their lymph nodes. An objective response rate of 51% ( $p < 0.0001$ ) consisting of 30 partial responses (PR) was achieved in the group of patients refractory to fludarabine and alemtuzumab. In the fludarabine refractory, alemtuzumab inappropriate patient group, an objective response rate of 44% ( $p < 0.0001$ ) was achieved, including 1 complete response (CR), and 34 PR. Achievement of the reported objective response rates are based on evaluations by an independent committee and are subject to review and confirmation by the regulatory authorities.

Ofatumumab was generally well tolerated by CLL patients in the study. The most frequently reported adverse events (those that occurred at a greater than 15% frequency) were: pyrexia, diarrhea, fatigue, cough, neutropenia, anemia and pneumonia. There were no unexpected safety findings. None of the 14 patients tested for human anti-human antibodies (HAHA) demonstrated their presence at 12 months.

A pre-BLA (Biologics License Application) meeting has been requested with the FDA during which these data will be discussed with the potential of a 2008 BLA filing. There is also the potential to submit to the EU regulatory authorities in this time frame. The full data will be submitted for presentation to an academic meeting in due course.

“We are thrilled to report a positive outcome for the CLL patients in this trial,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab. “This also represents a significant achievement for Genmab as we now move toward filing of the first marketing applications for a Genmab antibody and we look forward to working with GSK on the submissions.”

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“These very encouraging results suggest that ofatumumab has the potential to provide benefits to CLL patients with very refractory disease and limited treatment options,” said Kathy Rouan, Vice President and Medicine Development Leader at GSK. “GSK and Genmab are collaborating on a comprehensive development program for CLL as well as non-Hodgkin’s lymphoma (NHL), which we hope will make a significant contribution to the management of these haematologic malignancies for both patients and their physicians.”

Ofatumumab is an investigational new generation fully human monoclonal antibody that uniquely targets the 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 the trial**

The study includes CLL patients who are refractory to both fludarabine and alemtuzumab and patients who are refractory to fludarabine who are considered inappropriate candidates for alemtuzumab due to bulky tumor in their lymph nodes. All patients in the study receive 8 weekly infusions of ofatumumab, followed by 4 monthly infusions of ofatumumab. Patients receive 300 mg of ofatumumab at the first infusion and 2000 mg of ofatumumab at each subsequent infusion. Disease status is assessed every 4 weeks until week 28 and then every 3 months until disease progression or month 24. Patient recruitment is ongoing and a final analysis will be conducted on the full study population, expected to be 100 patients in each group.

The primary endpoint of the study is objective response over a 24 week period from start of treatment as assessed according to the National Cancer Institute Working Group guidelines. The secondary endpoints are duration of response, progression free survival, time to next CLL therapy, overall survival and adverse events.

## **Conference Call**

Genmab will hold a conference call to discuss these results today, July 31, 2008 at:

6:00 pm CEST

5:00 pm BST

12:00 pm EDT

The conference call will be held in English.

The dial in numbers are as follows:

+1 888 740 6137 (in the US) and ask for the Genmab conference call

+1 913 312 1480 (outside the US) and ask for the Genmab conference call

To listen to a live webcast of the call please visit [www.genmab.com](http://www.genmab.com).

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## 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).

## About GlaxoSmithKline

One of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

### *Forward Looking Statement for Genmab:*

*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 does not undertake any obligation to update or revise forward looking statements in this press release nor to confirm such statements in relation to actual results, unless required by law.*

Genmab<sup>®</sup>; the Y-shaped Genmab logo<sup>®</sup>; HuMax<sup>®</sup>; HuMax-CD4<sup>®</sup>; HuMax-CD20<sup>®</sup>; HuMax-EGFr<sup>™</sup>; HuMax-IL8<sup>™</sup>; HuMax-TAC<sup>™</sup>; HuMax-HepC<sup>™</sup>; HuMax-CD38<sup>™</sup>; HuMax-CD32b<sup>™</sup> and UniBody<sup>®</sup> are all trademarks of Genmab A/S.

### *GlaxoSmithKline Cautionary statement regarding forward-looking statements*

*Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2007.*

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