ARZERRA™ (OFATUMUMAB) DEMONSTRATES HIGH RESPONSE RATES IN PATIENTS WITH FLUDARABINE REFRACTORY CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL)

Data from a pivotal trial suggests that ofatumumab has activity in heavily pre-treated patients who had failed standard treatments

Summary: GlaxoSmithKline and Genmab A/S announce positive results from a pivotal trial pre-planned interim analysis of Arzerra™ (ofatumumab) in the treatment of refractory CLL.

Copenhagen, Denmark; December 8, 2008 – GlaxoSmithKline (GSK) and Genmab A/S (OMX: GEN) announced today positive results from a pivotal trial pre-planned interim analysis of Arzerra™ (ofatumumab) in the treatment of refractory chronic lymphocytic leukaemia (CLL). The results demonstrate the potential of ofatumumab as a new treatment option for heavily pre-treated patients with CLL who do not respond to, or are ineligible for currently available treatment options.[1] This research is being presented at the 50th Annual Meeting of the American Society of Hematology, 6-9 December, 2008. Ofatumumab is an investigational drug that has not been approved for any indication in any market at this time.

The analysis included 138 patients with CLL who showed limited or no response (refractory) to both fludarabine and alemtuzumab treatment (double refractory; DR), and patients who were refractory to fludarabine and considered inappropriate candidates for alemtuzumab due to bulky tumour masses in their lymph nodes (bulky fludarabine refractory; BFR).

The primary endpoint of the study was assessment of objective response.[i] The overall objective response rate seen in these patient groups treated with ofatumumab monotherapy was 58 percent for the DR group (n=59) and 47 percent for the BFR group (n=79); all responding patients had a partial response (PR[ii]) except for one patient with a complete response (CR[iii]).[1] Median overall survival was 13.7 months for the DR group and 15.4 months for the BFR group;[1] response to ofatumumab treatment significantly correlated with longer patient survival. The median length of time that a patient lived without their disease getting worse (progression free survival) was 5.7 months for the DR group and 5.9 months for the BFR group.[1]

[i] The percentage of patients whose tumour shrinks or disappears after treatment
[ii] A decrease in the extent of cancer in the body, in response to treatment
[iii] The disappearance of all signs of cancer in response to treatment.

The results are summarised in the table below:

	DR Patient Group	BFR Patient Group
Objective response rate	58 percent	47 percent
Median overall survival	13.7 months	15.4 months
Progression free survival	5.7 months	5.9 months

The most common adverse event seen was infusion related reactions which were mostly mild to moderate in severity. The most common serious adverse events (Grade 3 or 4) were infections (25 percent in DR; 25 percent in BFR), including 1 case of progressive multifocal leukoencephalopathy (PML) in a patient with progressive disease. Early death (within eight weeks from start of treatment) occurred in four patients (7 percent) in the DR group and two patients (3 percent) in the BFR group. No patient tested positive for antibodies to ofatumumab.[1]

“There is a great unmet medical need among patients with CLL that is refractory to conventional therapy. The clinical responses and the tolerability profile we are seeing with ofatumumab in this group of CLL patients are very encouraging,” said lead investigator Professor Anders Österborg, Department of Hematology, Karolinska Hospital, Stockholm, Sweden.

In a post hoc, subset analysis prior treatment with rituximab did not have a significant effect on ofatumumab treatment efficacy. Of those patients who had received prior rituximab-containing therapy 54 percent in the DR group and 44 percent in the BFR group responded to treatment with ofatumumab.[1]

“The positive results seen in this interim analysis reinforce the potential of ofatumumab in the treatment of CLL refractory to standard treatments," said Moncef Slaoui, Chairman Research and Development at GSK. “We are committed to the development of ofatumumab in both CLL and other disease settings to provide an additional treatment option to patients suffering from haematological malignancies.”

“Ofatumumab has helped responding patients who did not have other treatment options,” said Lisa N. Drakeman, Chief Executive Officer of Genmab. “We are working together with GSK to bring this urgently needed new medicine to market as quickly as possible, and are currently collaborating on filing submissions.”

Genmab and GSK now expect to file a Biologics License Application (BLA) filing with the US FDA in January 2009.

CLL is the most common form of leukaemia in the Western world,[2] and the treatment of patients with refractory disease remains a significant challenge. Patients who have not responded to current standard therapies; specifically patients whose disease is refractory to fludarabine and alemtuzumab treatment or patients who are refractory to fludarabine but ineligible for alemtuzumab, experience poorer outcomes. Only about 20 percent of patients respond to available salvage therapies.[3] Currently there is no approved drug for the treatment of this patient population.

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Ofatumumab is a novel, next-generation, investigational monoclonal antibody that targets a distinct membrane-proximal (close to the cell surface), small loop epitope (a portion of a molecule to which an antibody binds) on the CD20 molecule on B cells.[4] This epitope is different from the binding sites targeted by other CD20 antibodies currently available or in development.[5] The CD20 molecule is a key target in CLL therapy because it is expressed in most B cell malignancies.[6]

About the study[1]
The study includes patients with CLL refractory to both fludarabine and alemtuzumab, and patients who are refractory to fludarabine and considered inappropriate candidates for alemtuzumab due to bulky tumour masses in their lymph nodes. The study design calls for patients to receive eight weekly infusions of ofatumumab, followed by four monthly infusions. Patients receive 300 mg of ofatumumab at the first infusion and 2,000 mg of ofatumumab at each subsequent infusion. Disease status is assessed every four weeks until week 28 and then every three months until disease progression or month 24.

The interim analysis included 138 treated patients (DR, n=59; BFR, n=79). 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 by an Independent endpoint Review Committee (IRC). The secondary endpoints are duration of response, progression free survival, time to next CLL therapy, overall survival and adverse events.

About ofatumumab
Ofatumumab is being developed to treat chronic lymphocytic leukaemia, follicular non-Hodgkin's lymphoma, diffuse large B cell lymphoma, rheumatoid arthritis and relapsing-remitting multiple sclerosis under a co-development and commercialisation agreement between Genmab and GlaxoSmithKline. It is not yet approved for any indication in any country.

About CLL
CLL is the most common leukaemia and one of the most common malignant lymphoid diseases in the Western world.[7] Globally, leukaemia accounts for some 300,000 new cases each year (2.8% of all new cancer cases) and 222,000 deaths.[8]

Conference Call
Genmab will hold a conference call to discuss these results tomorrow, December 9, 2008 at:
3:00 pm CET
2:00 pm GMT
9:00 am EST

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The conference call will be held in English.

The dial in numbers are as follows:
+1 877 723 9518 (in the US) and ask for the Genmab conference call
+1 719 325 4812 (outside the US) and ask for the Genmab conference call

To listen to a live webcast of the call please visit www.genmab.com.

GSK in Oncology
GSK Oncology is dedicated to producing innovations in cancer that will make profound differences in the lives of patients. Through GSK's revolutionary 'bench to bedside' approach, we are transforming the way treatments are discovered and developed, resulting in one of the most robust pipelines in the oncology sector. Our worldwide research in oncology includes collaborations with more than 160 cancer centres. GSK is closing in on cancer from all sides with a new generation of patient focused cancer treatments in prevention, supportive care, chemotherapy and targeted therapies.

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. For further information please visit www.gsk.com

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.

Notes to Editors:
Refractory - term used to describe a disease that does not respond to treatment or returns within six months of completing such treatment
Bulky tumours - when individual tumour masses are >5cm in diameter
Salvage therapy - a final treatment for people who are non-responsive to or cannot tolerate other available therapies for a particular condition and whose prognosis is often poor

Arzerra™ is the proposed registered trademark to be used in the United States and Europe.

To access the latest GSK Oncology media materials, visit www.gskcancermedia.com

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Cautionary statement regarding forward-looking statements for GSK
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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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. 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.

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