

GlaxoSmithKline and Genmab Submit Arzerra™ (Ofatumumab) Application to FDA for the Treatment of Advanced Stage Blood Cancer

Three New Studies Initiated in Other Oncology Settings

LONDON, UK AND COPENHAGEN, DENMARK, January 30, 2009 – GlaxoSmithKline (GSK) and Genmab A/S (OMX: GEN) announced today the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Arzerra™ (ofatumumab) to treat patients whose chronic lymphocytic leukemia (CLL) is resistant (refractory) to previous therapies. If approved, ofatumumab would be the first anti-CD20 monoclonal antibody available for this patient population.

CLL is the most common form of adult leukemia in the Western world,^{1,2} affecting more than 90,000 Americans.³ Patients with refractory CLL need new therapies since less than 25 percent respond to most current treatments while still having to cope with adverse effects.⁴

“The submission of the BLA for ofatumumab brings us closer to the possibility of providing a new treatment to patients with refractory CLL,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab. “This is the first BLA ever filed for an antibody produced by Genmab and is a significant achievement in our partnership with GSK.”

The submission is based on an analysis that included 138 patients with CLL who showed limited or no response to both fludarabine and alemtuzumab treatment (fludarabine alemtuzumab refractory) and patients who were refractory to fludarabine and considered inappropriate candidates for alemtuzumab due to bulky tumor masses (>5 cm) in their lymph nodes (bulky fludarabine refractory). The primary endpoint of the study was assessment of response. The overall response rate seen in these patient groups treated with single-agent ofatumumab was 58 percent for the fludarabine alemtuzumab refractory group (n=59) and 47 percent for the bulky fludarabine refractory group (n=79).^{5,6}

The most common adverse events (AEs) seen with ofatumumab were related to infusion reactions and infections. AEs seen in at least 10 percent of patients included fever, cough, diarrhea, rash, low white blood cell counts, fatigue, pneumonia, anemia, shortness of breath and nausea. In clinical trials to date, infusion reactions that were serious yet manageable were seen in three percent of patients. One case of progressive multifocal leukoencephalopathy (PML), a rare brain infection resulting in death or causing severe disability, and one case of tumor lysis syndrome were reported.^{5,6} These data were presented at the 50th Annual Meeting of the American Society of Hematology (ASH) in December 2008.

Potential to Combat CLL in Earlier Stages

The companies also announced today the initiation of an additional Phase III study of ofatumumab in combination with fludarabine and cyclophosphamide (FC) for patients with CLL when initial treatment no longer works (second-line treatment). The open-label study will randomize 352 patients to evaluate progression-free survival (PFS) of ofatumumab in combination with FC therapy versus FC therapy alone for the treatment of relapsed CLL.⁷ Enrollment for this study will begin shortly.

“Bolstered by the positive results of ofatumumab for advanced stage CLL, we’re now investigating ofatumumab in earlier stages in the treatment continuum,” said Paolo Paoletti, M.D., Senior Vice President of Oncology R&D, GSK. “The clues we’re seeing from ofatumumab also suggest possible activity in other oncology settings, which we’re currently evaluating through several clinical trials.”

GSK and Genmab will conduct additional studies of ofatumumab in CLL and non-Hodgkin’s lymphoma (NHL) settings. In CLL, a Phase III front-line study is evaluating ofatumumab combined with chlorambucil in patients with previously untreated CLL. In NHL, an ongoing Phase II study will assess ofatumumab in patients with Waldenstrom’s Macroglobulinemia – a rare type of slow-growing NHL.⁸ Finally, a Phase II study is evaluating ofatumumab plus ICE or DHAP chemotherapy regimen in relapsed/refractory diffuse large B-cell lymphoma (DLBCL).

About ofatumumab

Ofatumumab is an investigational monoclonal antibody that targets a 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.⁹ This epitope is different from the binding sites targeted by other CD20 antibodies currently available.¹⁰ The CD20 molecule is a key target in CLL therapy because it is highly expressed in most B-cell malignancies.¹¹

Ofatumumab is being developed to treat chronic lymphocytic leukemia, 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.

The companies intend to submit an application for marketing approval in Europe shortly.

About CLL

CLL is the most common adult leukemia^{1,2} and one of the most common malignant lymphoid diseases.¹² Based on 2007 worldwide estimates, leukemia accounted for more than 330,000 new cases and more than 245,000 deaths.¹³

CLL cells are malignant B-cells¹⁴ that have low surface expression levels of CD20 molecules.⁹ B-cells normally protect the body from invading pathogens by developing into plasma cells, which make antibodies. These antibodies directly inactivate pathogens or attach to pathogens to prepare them for destruction by other white blood cells.^{14,15}

GlaxoSmithKline (GSK)

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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 centers. 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.

About Genmab A/S

Genmab is a leading international biotechnology company focused on developing fully human antibody therapeutics for the potential treatment of cancer. Genmab's world class discovery, development and manufacturing teams are using cutting-edge technology to create and develop products to address unmet medical needs. Our primary goal is to improve 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.

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

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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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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.

References

- 1 American Cancer Society. Cancer Facts and Figures 2008. <http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf>. Accessed January 28, 2009.
- 2 Eichhorst B. Chronic lymphocytic leukemia: ESMO Clinical Recommendations for diagnosis, treatment and follow-up. *Ann Oncol* 2008. 19:60-62. doi:10.1093/annonc/mdn090.
- 3 Leukemia and Lymphoma Society. "Facts 2008-2009." http://www.leukemia-lymphoma.org/attachments/National/br_1215783647.pdf. Accessed January 28, 2009.
- 4 Tam CS, O'Brien S, et al. The natural history of fludarabine-refractory chronic lymphocytic leukemia patients who fail alemtuzumab or have bulky lymphadenopathy. *Leukemia and Lymphoma*. 2007;48(10):1931-1939.
- 5 Osterborg A, Kipps et al. Ofatumumab (HuMax-CD20), a Novel CD20 Monoclonal Antibody, Is An Active Treatment for Patients with CLL Refractory to Both Fludarabine and Alemtuzumab or Bulky Fludarabine-Refractory Disease: Results from the Planned Interim Analysis of An International Pivotal Trial. Abstract #328. Presented at the American Society of Hematology Annual Meeting 2008.
- 6 Osterborg A, Kipps et al. Ofatumumab (HuMax-CD20), a Novel CD20 Monoclonal Antibody, Is An Active Treatment for Patients with CLL Refractory to Both Fludarabine and Alemtuzumab or Bulky Fludarabine-Refractory Disease: Results from the Planned Interim Analysis of an International Pivotal Trial. Oral Presentation of Abstract #328. Presented at the American Society of Hematology Annual Meeting 2008.
- 7 Available at www.clinicaltrials.gov.
- 8 National Cancer Institute. "Waldenström Macroglobulinemia: Questions and Answers." <http://www.cancer.gov/cancertopics/factsheet/Sites-Types/WM>. Accessed January 15, 2009.
- 9 Hagenbeek A, Gadeberg O, et al. First clinical use of ofatumumab, a novel fully human anti-CD20 monoclonal antibody in relapsed or refractory follicular lymphoma: results of a phase 1/2 trial. *Blood*. 2008;111:5486-5495.
- 10 Teeling JL, Mackus, W, J., et al. The Biological Activity of Human CD20 Monoclonal Antibodies Is Linked to Unique Epitopes on CD20. *J Immunol*. 2006;177:362-371.
- 11 Glennie MJ, French RR, et al. Mechanisms of killing by anti-CD20 monoclonal antibodies. *Molecular Immunology*. 2007;44(16):3823-3837.
- 12 Shanafelt TD, Byrd JC, et al. Narrative review: initial management of newly diagnosed, early-stage chronic lymphocytic leukemia. *Ann Intern Med*. 2006;145(6):435-47.
- 13 American Cancer Society. Global Cancer Facts and Figures 2007. http://www.cancer.org/downloads/STT/Global_Facts_and_Figures_2007_rev2.pdf. Accessed January 28, 2009.
- 14 American Cancer Society. "Leukemia – Chronic Lymphocytic." <http://documents.cancer.org/6893.00/6893.00.pdf>. Accessed January 21, 2009.
- 15 "Chronic Lymphocytic Leukemia." The Leukemia & Lymphoma Society. http://www.leukemia-lymphoma.org/attachments/National/br_1172585237.pdf. Accessed January 21, 2009.