

ARZERRA™ (OFATUMUMAB) RECEIVES POSITIVE OPINION FOR CONDITIONAL APPROVAL IN EUROPE FOR REFRACTORY CHRONIC LYMPHOCYTIC LEUKAEMIA

Summary: GSK and Genmab have received a positive opinion for conditional approval of Arzerra (ofatumumab) in Europe for CLL that is refractory to fludarabine and alemtuzumab.

Copenhagen, Denmark; January 22, 2010 –GlaxoSmithKline (GSK) and Genmab A/S (OMX: GEN) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Arzerra™ (ofatumumab), for the treatment of refractory chronic lymphocytic leukaemia (CLL).

The CHMP has recommended the conditional marketing authorisation of ofatumumab in the European Union for the treatment of patients with CLL who are refractory to fludarabine and alemtuzumab. Fludarabine and alemtuzumab are standard therapies currently used to treat CLL (*Abbott 2006/Robak 2008*).

Chronic lymphocytic leukaemia is a cancer of the blood and bone marrow. In patients with CLL who have not responded to treatment, or who have disease progression within six months to the latest treatment, the disease is termed refractory. Patients with refractory CLL have limited treatment options and poor outcomes with existing treatments (*Keating 2002*). Less than 25% of these patients respond to existing treatments (*Tam et al, 2007*).

About conditional marketing authorisation

A conditional marketing authorisation is granted to a medicinal product with a positive benefit/risk assessment that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorisation is renewable annually. As part of the conditions of the conditional marketing authorisation for ofatumumab, GSK will be required to provide further data.

About ofatumumab

Ofatumumab is a novel human monoclonal antibody with a unique mode of action. It targets, a unique part of the CD20 molecule encompassing an epitope in the small loop (*Teeling et al 2006*). The CD20 molecule is a key target in CLL therapy, because it is expressed in most B cell malignancies (*Cragg et al 2005*).

About Genmab

Genmab A/S is a leading international biotechnology company focused on developing fully human antibody therapeutics for the potential treatment of cancer. Genmab's world class discovery and development 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

ARZERRA™ (OFATUMUMAB) RECEIVES POSITIVE OPINION FOR CONDITIONAL APPROVAL IN EUROPE FOR REFRACTORY CHRONIC LYMPHOCYTIC LEUKAEMIA

who are in urgent need of new treatment options. For more information on Genmab's products and technology, visit www.genmab.com.

About 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.

About GlaxoSmithKline

GSK Biopharm R&D is employing novel approaches to harness the therapeutic potential of biopharmaceuticals for the benefit of patients with serious disease. This innovative research is one way GSK – one of the world's leading research-based pharmaceutical and healthcare companies – can deliver on its commitment to improving the quality of human life by enabling people to do more, feel better and live longer. For more information, visit GlaxoSmithKline on the World Wide Web at www.gsk.com.

Notes to editors:

Arzerra® is a registered trade mark of the GlaxoSmithKline group of companies in the US and the proposed trade name in Europe, Asia-Pacific, Japan, and emerging countries.

This Stock Exchange 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 Stock Exchange Release nor to confirm such statements in relation to actual results, unless required by law.

Genmab®, the Y-shaped Genmab logo®, HuMax®, HuMax-CD20®, HuMax-EGFr™, HuMax-IL8™, HuMax-TAC™, HuMax-HepC™, HuMax-CD38™, HuMax-CD32b™, HuMax-TF™, HuMax-Her2™, HuMax-VEGF™ and UniBody® are all trademarks of Genmab A/S. Arzerra™ is a trademark of GlaxoSmithKline.

Contact: Helle Husted, Vice President, Investor Relations
T: +45 33 44 77 30; M: +45 25 27 47 13; E: h.husted@genmab.com

References

Genmab A/S
Bredgade 34
1260 Copenhagen K, Denmark
Tel: +45 7020 2728
Fax: +45 7020 2729
CVR no. 2102 3884

Stock Exchange Release no. 2/2010
Page 2/3

ARZERRA™ (OFATUMUMAB) RECEIVES POSITIVE OPINION FOR CONDITIONAL APPROVAL IN EUROPE FOR REFRACTORY CHRONIC LYMPHOCYtic LEUKAEMIA

Abbott BL. Chronic lymphocytic leukaemia: recent advances in diagnosis and treatment. *Oncologist* 2006;11(1):21-30.

Cragg, M. S., C. A. Walshe, et al. The biology of CD20 and its potential as a target for mAb therapy. *Curr Dir Autoimmun* 2005; 8: 140-74.

Keating, M. J., S. O'Brien, et al. (2002). Results of first salvage therapy for patients refractory to a fludarabine regimen in chronic lymphocytic leukemia. *Leuk Lymphoma* 43(9): 1755-62.

Robak T. Novel monoclonal antibodies for the treatment of chronic lymphocytic leukemia. *Curr Cancer Drug Targets* 2008; 8:156-171.

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.

Teeling JL, Mackus WJ, Wiegman LJ, et al. The biological activity of human CD20 monoclonal antibodies is linked to unique epitopes on CD20. *J Immunol* 2006; 177:362-71.

###