



## **ARZERRA™ (OFATUMUMAB) MAA ACCEPTED BY EMEA**

*Summary: The EMEA has confirmed the Marketing Authorization Application for Arzerra is valid and that the review procedure has started.*

**Copenhagen, Denmark; February 26, 2009** – Genmab A/S (OMX: GEN) announced today that the European Medicines Agency (EMA) has confirmed the Marketing Authorization Application (MAA) for Arzerra™ (ofatumumab) for the treatment of chronic lymphocytic leukemia (CLL) is valid and that the review procedure started on February 25, 2009. If approved, ofatumumab would be indicated for the treatment of patients with CLL who have previously failed, or are inappropriate for, standard therapies. The MAA was submitted on February 5, 2009.

The acceptance of the MAA will trigger a milestone payment from GlaxoSmithKline to Genmab of DKK 58 million (approximately USD 10 million).

“We are excited to reach this important milestone so soon after submitting the Arzerra™ MAA to the European regulatory authorities,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab.

### **About ofatumumab**

Ofatumumab is a novel, investigational, fully human 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 of B-cells. This epitope is different from the binding sites targeted by other CD20 antibodies currently available. The CD20 molecule is a key target in CLL therapy because it is expressed on most B-cells in CLL patients. In Europe, ofatumumab has been granted orphan designation for CLL as it affects approximately 3.5 in 10,000 persons in the European Union.

Ofatumumab is being developed 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 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](http://www.genmab.com).

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*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®; 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](mailto:h.husted@genmab.com)

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