# FDA Grants GSK and Genmab's Arzerra® (Ofatumumab) Breakthrough Therapy Designation for Previously Untreated Chronic Lymphocytic Leukemia

## Company Announcement

- **Ofatumumab receives Breakthrough Therapy designation in CLL**
- **Potential for expedited development**

**Copenhagen, Denmark; September 13, 2013 – Genmab A/S (OMX: GEN) and GlaxoSmithKline plc (GSK) announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for Arzerra® (ofatumumab) in combination with chlorambucil for the treatment of patients with chronic lymphocytic leukemia (CLL) who have not received prior treatment and are inappropriate for fludarabine-based therapy.** Ofatumumab is not approved or licensed anywhere in the world for use in this treatment setting. Breakthrough Therapy designation is the newest of the FDA's programs aimed at accelerating the development and review times of drugs for serious or life-threatening conditions.

CLL is the most common form of leukemia in adults. Based on estimates by the American Cancer Society, CLL will account for more than 15,680 new cases and more than 4,580 deaths in the United States of America alone in 2013. At present, no curative chemotherapy is available.

The Breakthrough Therapy designation was based on the results from an international, multicenter, randomized Phase III clinical trial in more than 400 patients with previously untreated CLL. Headline results from this trial were announced in May 2013 and the full study results have been submitted for presentation at the 2013 American Society of Hematology Annual Meeting in December.

"We are exceedingly proud to receive the Breakthrough Therapy designation, the second this year for GSK. This FDA program is intended to expedite not just the development but also the review of drugs for serious or life threatening conditions," said Dr. Kathy Rouan, Vice President and Head of Biopharmaceutical Development, GlaxoSmithKline. "We are actively working on our submission and look forward to the enhanced regulatory interaction allowed for Breakthrough Therapies."

"Both of Genmab's lead products, ofatumumab and daratumumab, have now been granted Breakthrough Therapy designations from the FDA. This designation for ofatumumab reflects Genmab's mission to create differentiated products aimed at improving the lives of patients suffering from debilitating diseases and for whom existing treatments are inadequate," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

**About Breakthrough Therapy designation**
The Breakthrough Therapy designation was enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA) and is intended to expedite development and review of drugs to treat serious or life-threatening medical conditions when preliminary clinical evidence demonstrates that the drug may have substantial improvement on at least one clinically significant endpoint over available therapies. Breakthrough Therapy designation includes all the features of the Fast Track designation, as well as more intensive guidance from the FDA on a drug's clinical development program.

**About ofatumumab**
Ofatumumab is a human monoclonal antibody which targets an epitope on the CD20 molecule encompassing parts of the small and large extracellular loops[i]. Ofatumumab is being developed under a co-development and commercialization agreement between Genmab and GSK. For Full US Prescribing Information for the approved indication, please visit: us.gsk.com/html/medicines/index.html and visit health.gsk.com for the EU SPC for the approved indication.

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**About Genmab A/S**
Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company's first marketed antibody, ofatumumab (Arzerra®), was approved to treat chronic lymphocytic leukemia in patients who are refractory to fludarabine and alemtuzumab after less than eight years in development. Genmab's validated and next generation antibody technologies are expected to provide a steady stream of future product candidates. Partnering of innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

**About GSK**
GSK – 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.


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*Forward Looking Statement for Genmab*
*This Company Announcement 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 pre-clinical and clinical development of products, 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 risk*

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*management sections in Genmab's most recent financial reports, which are available on www.genmab.com. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements in relation to actual results, unless required by law.*



## *Cautionary statement regarding forward-looking statements for GSK*

*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 Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.*

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[i] Teeling JL, Mackus WJ, Wiegman LJ, van den Brakel JH, Beers SA, French RR, et al. The biological activity of human CD20 monoclonal antibodies is linked to unique epitopes on CD20. J Immunol. 2006;177(1):362–71