

GSK and Genmab Announce Submission to US Regulatory Authorities for Arzerra® (Ofatumumab) as 1st Line Treatment of Chronic Lymphocytic Leukemia (CLL)

Company Announcement

- sBLA submitted to US FDA for Arzerra in 1st line CLL
- Follows recent EU application for expanded label of Arzerra

Copenhagen, Denmark; October 18, 2013 – GlaxoSmithKline (GSK) and Genmab A/S (OMX: GEN) announced today the submission of a supplemental Biologics License Application (sBLA) to the US Food and Drug Administration (FDA) for the use of Arzerra (ofatumumab) in combination with an alkylator-based therapy, to be used for treatment of CLL patients who have not received prior treatment and are inappropriate for fludarabine-based therapy.

The application is based on results from an international, multi-center, randomized Phase III study of Arzerra in combination with chlorambucil versus chlorambucil alone in more than 400 patients with previously untreated CLL. Headline results from this trial were announced in May 2013 and the full study results are scheduled to be presented in two oral presentations at the 2013 American Society of Hematology Annual Meeting in December.

About Chronic Lymphocytic Leukemia

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 2013.¹ At present, no curative chemotherapy is available.

About Arzerra (ofatumumab)

Ofatumumab is not approved or licensed anywhere in the world for use in patients who have not received treatment for CLL. For the approved indication, please visit <u>http://us.gsk.com/html/medicines/index.html</u> for full US Prescribing Information and <u>http://health.gsk.com/</u> for the EU Summary of Product Characteristics (SPC).

Ofatumumab is a human monoclonal antibody which targets an epitope on the CD20 molecule encompassing parts of the small and large extracellular loops². Ofatumumab is being developed under a co-development and collaboration agreement between Genmab and GlaxoSmithKline.

About 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 <u>www.gsk.com</u>.

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 <u>www.genmab.com</u>.

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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 management sections in Genmab's most recent financial reports, which are available on <u>www.genmab.com</u>. 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.

Genmab A/S and its subsidiaries own the following trademarks: Genmab[®]; the Y-shaped Genmab logo[®]; Genmab in combination with the Y-shaped Genmab logo[™]; the DuoBody[™] logo; HuMax[®]; HuMax-CD20[®]; DuoBody[®], HexaBody[™] and UniBody[®]. Arzerra[®] is a registered trademark of GlaxoSmithKline.

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.

Registered in England & Wales: No. 3888792 Registered Office: 980 Great West Road Brentford, Middlesex TW8 9GS

¹American Cancer Society, *Estimated Number of New Cancer Cases and Deaths by Sex, US, 2013*, <u>http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-037124.pdf</u>, accessed September 18, 2013.

² Teeling et al, *J Immunol* 2006; 177:362-371

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