



# GSK AND GENMAB ANNOUNCE TOPLINE RESULTS FROM THE CONCLUDED PIVOTAL TRIAL OF ARZERRA (OFATUMUMAB) IN FLUDARABINE AND ALEMTUZUMAB REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA

Summary: GSK and Genmab announce top-line results from the concluded pivotal trial of of atumumab in patients with fludarabine-refractory CLL.

**London, UK; Copenhagen, Denmark; August 9, 2010** – GlaxoSmithKline (GSK) and Genmab A/S (OMX: GEN) announced today topline results from the concluded pivotal trial of ofatumumab in patients with fludarabine and alemtuzumab refractory chronic lymphocytic leukemia (CLL).

Ofatumumab was given accelerated approval by the US Food and Drug Administration (FDA) on October 26, 2009 for the treatment of patients with CLL who are refractory to fludarabine and alemtuzumab treatment based on the interim results from this trial in 59 patients. On April 19, 2010, the European Commission granted a conditional marketing authorization to Arzerra<sup>TM</sup> (ofatumumab) for the treatment of chronic lymphocytic leukaemia (CLL) in patients who are refractory to fludarabine and alemtuzumab.

A total of 95 patients with fludarabine and alemtuzumab refractory CLL were treated in the study. The objective response rate (ORR), as determined by an Independent Review Committee, in the study was 51%. In addition to the 95 patients in the efficacy analysis the study also included 128 patients with relapsed or refractory CLL, who were not refractory to both fludarabine and alemtuzumab.

There were no unexpected safety findings reported with the total study population (n=223). The most common adverse reactions ( $\geq$ 10%) occurring in patients treated with Arzerra were pyrexia (21%), anemia (18%), diarrhea (17%), neutropenia, fatigue (16%), dyspnea (15%), pneumonia (15%), chills (13%), rash (13%), nausea (13%), bronchitis (12%), peripheral edema (11%), back pain (10%) and upper respiratory tract infection (10%).

Results from this concluded pivotal trial are consistent with the efficacy and safety data reported in the interim analysis and demonstrate the activity of single-agent of atumumab in patients with heavily pretreated fludarabine and alemtuzumab-refractory chronic lymphocytic leukemia.

### About of atumumab

Ofatumumab is a human monoclonal antibody. Ofatumumab binds specifically to both the small and large extracellular loops of the CD20 molecule. The CD20 molecule is expressed on normal B lymphocytes (pre-B- to mature B-lymphocytes) and on B-cell CLL. In vitro data suggest that

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possible mechanisms of cell lysis include complement-dependent cytotoxicity and antibodydependent cell-mediated cytotoxicity.

### About GlaxoSmithKline

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 company information, visit GlaxoSmithKline at <u>http://www.gsk.com</u>.

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

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