GSK and Genmab announce top-line results from a Phase III study of ofatumumab versus physicians' choice for bulky fludarabine-refractory CLL

Company Announcement

- **Trial did not meet the primary endpoint of Progression Free Survival**
- **Data to be further analyzed in the coming months**

Copenhagen, Denmark; June 27, 2014 – GlaxoSmithKline plc (LSE: GSK) and Genmab A/S (OMX: GEN) announced today that the Phase III study of ofatumumab (Arzerra™) versus physicians' choice in patients with bulky fludarabine-refractory chronic lymphocytic leukaemia (CLL) did not meet its primary endpoint of progression free survival (PFS). The median PFS, as assessed by the Independent Review Committee, was 5.36 months for ofatumumab and 3.61 months for physicians' choice (Hazard Ratio 0.79, p=0.267).

The result reported today is headline data; the full analysis of safety and efficacy data is underway and will be completed in the coming months. This study (OMB114242) was conducted to meet the requirements from the EU Commission for the conditional approval of ofatumumab for the treatment of CLL in patients who are refractory to fludarabine and alemtuzumab. The current indications in the EU or US do not include bulky fludarabine-refractory CLL patients.

"It was our priority to share this result with the scientific community as soon it became available. We will now work to further analyse the data and to better understand the totality of the efficacy and safety findings," said Dr. Rafael Amado, Head of Oncology R&D at GSK. "We are very grateful to the CLL patients who participated in this trial."

"Although ofatumumab performed broadly in-line with previous data, today's result is disappointing. Based on this result, we do not anticipate applying for a label expansion for ofatumumab in this specific refractory CLL population," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the study

This Phase III open-label study randomised 122 patients with bulky fludarabine-refractory CLL to one of two treatment arms. Patients were randomised to either ofatumumab or physicians' choice (2:1). Patients randomised to ofatumumab received an initial dose of 300 mg, followed 1 week later by 2,000 mg once weekly for 7 weeks, followed 4 weeks later by one infusion of 2,000 mg every 4 weeks for a total treatment duration of 6 to 12 months. Patients in the physicians' choice arm received a treatment regimen chosen by a physician for up to six months.

The primary endpoint of the study was progression free survival as adjudicated by the Independent Review Committee. Secondary objectives are to evaluate response, overall survival, safety, tolerability and health-related quality of life of subjects treated with ofatumumab versus physicians' choice of treatment.

About CLL

CLL, the most commonly diagnosed adult leukaemia in Western countries, accounts for approximately one-third of all cases of leukaemia. [1,2,3] In the U.S., it is estimated that more than 105,000 people currently live with or have been previously treated for CLL and an estimated 15,680 new cases of CLL were diagnosed in the past year. [3,4] The average age of diagnosis is 72 years old, and approximately 90 per cent of patients with CLL are estimated to be over the age of 55. [3,5] The majority of patients with CLL have at least one comorbidity such as hypertension, diabetes, cardiovascular disease, or COPD. [6]

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Important Safety Information

The following Important Safety Information is based on the Highlights section of the Prescribing Information for Arzerra. Please consult the full prescribing information for all the labeled safety information for Arzerra.

The most common adverse reactions (≥10%) seen in previously untreated CLL patients were infusion reactions, neutropenia, rash, anaemia, and respiratory tract infections. Much less common but potentially very serious adverse reactions include severe infusion reactions, hepatitis B virus reactivation, hepatitis B virus infection, progressive multifocal leukoencephalopathy, and tumor lysis syndrome.

For full **U.S. Prescribing Information, including Boxed Warning, visit** **https://www.gsksource.com/gskprm/htdocs/documents/ARZERRA.PDF**. For the approved indications and European Union (EU) Summary of Product Characteristics (SPC) visit http://health.gsk.com/.

About ofatumumab (Arzerra)

Ofatumumab is a monoclonal antibody that is designed to target the CD20 molecule found on the surface of CLL cells and normal B lymphocytes.

In the U.S., ofatumumab is approved for use in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate. Ofatumumab is also approved for first-line use in Russia.

In more than 50 countries worldwide, ofatumumab is indicated as monotherapy for the treatment of patients with CLL refractory to fludarabine and alemtuzumab.

Ofatumumab is being developed under a co-development and collaboration agreement between Genmab and GSK.

Arzerra is a trademark of the GSK group of companies.

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.

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 currently has one marketed antibody, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications, a clinical pipeline with both late and early stage programs, and an innovative pre-clinical pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody® platform for generation of bispecific antibodies, and the HexaBody™ platform which creates effector function enhanced antibodies. Genmab's deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected 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.

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Cautionary statement regarding forward-looking statements
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. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2013.

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 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.

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