Genmab Announces Positive Top-Line Phase II Results of Ofatumumab in Multiple Sclerosis

Company Announcement

- **Treatment with ofatumumab showed significant reduction in the cumulative number of new brain lesions**
- **No unexpected safety findings**

Copenhagen, Denmark; October 10, 2013 – Genmab A/S (OMX: GEN) announced today top-line results from a Phase II study of the subcutaneous formulation of ofatumumab in relapsing-remitting multiple sclerosis (RRMS).

A total of 232 subjects with RRMS were randomized in the study. There was a clear separation from placebo on the cumulative number of new gadolinium enhancing lesions (active brain lesions) over a period of 12 weeks in subjects treated with all doses of ofatumumab compared to subjects treated with placebo [$p < 0.001$]. For the primary endpoint, analysis of data from weeks 0-12 estimated a 65% reduction in the cumulative number of new T1 gadolinium enhancing lesions for all doses [$p < 0.001$]. In weeks 4-12, analyses of data estimated a ≥ 90% reduction in the cumulative number of new T1 gadolinium enhancing lesions for all cumulative doses of ofatumumab ≥ 30 mg [$p < 0.001$].

There were no unexpected safety findings in the study. From weeks 0-12, injection related reactions were the most common adverse reaction and were observed in 52% of subjects receiving ofatumumab compared to 15% of subjects receiving placebo. There were five serious adverse events (SAEs) reported, all subjects received a 60 mg dose of ofatumumab and none of these subjects withdrew from the study. Twelve subjects withdrew during this time period; 10 of these subjects were receiving ofatumumab. To date, no cases of progressive multifocal leukoencephalopathy (PML) or opportunistic infections have been observed.

“We are encouraged by the results from this study, which we believe underline the potential of subcutaneous ofatumumab for treatment of relapsing-remitting multiple sclerosis,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the study

This multi-center, randomized, double-blind, placebo controlled Phase II study, conducted by GlaxoSmithKline (GSK), included subjects who had RRMS. The primary objective of the study was to determine whether 3, 30 or 60 mg of ofatumumab given subcutaneously reduces the number of new T1-weighted gadolinium-enhancing brain lesions (active brain lesions) over a period of 12 weeks, as compared with placebo, in subjects with RRMS.

Subjects in the study were randomized to one of the following treatment arms: 3 mg, 30 mg, or 60 mg of subcutaneous ofatumumab every 12 weeks or 60 mg of subcutaneous ofatumumab every 4 weeks, or placebo followed by 3 mg of subcutaneous ofatumumab at week 12. The treatment period for all subjects was 24 weeks; subjects were then followed until B-cell repletion for at least an additional 24 weeks. Currently, all subjects have completed the 24-week treatment period; some subjects continue to be followed as per protocol.

About RRMS

Multiple Sclerosis (MS) is an inflammatory disease of the central nervous system. MS is twice as common in females as in males, occurring with a peak incidence at the age of 35 years and incidence varies widely in different populations and ethnic groups. The etiology of MS remains unknown, but the geographic variation points towards possible environmental and genetic factors. The most common form of MS is relapsing-remitting MS (RRMS) characterized by unpredictable recurrent attacks where the symptoms usually evolve over days and are followed by either complete, partial or no neurological recovery.

Genmab Announces Positive Top-Line Phase II Results of Ofatumumab in Multiple Sclerosis

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 collaboration agreement between Genmab and GSK. Under the companies' agreement, GSK is solely responsible for development of ofatumumab in autoimmune indications and all related costs.

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.

Contact:
Rachel Curtis Gravesen, Senior Vice President, Investor Relations & Communications
T: +45 33 44 77 20; M: +45 25 12 62 60; E: r.gravesen@genmab.com

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.

[i] Teeling et al, J Immunol 2006