

## Genmab Collaborator GSK Starts New Ofatumumab Phase III Study in Rare Skin Disorder

### Company Announcement

- **First Phase III study with subcutaneous formulation of ofatumumab**
- **Ofatumumab to be investigated in new autoimmune area – pemphigus vulgaris**
- **Patient recruitment in Phase III study to start soon**

**Copenhagen, Denmark; July 4, 2013 – Genmab A/S (OMX: GEN) announced today that GSK will start a new Phase III study of ofatumumab given subcutaneously to treat pemphigus vulgaris, a rare autoimmune disorder of the skin.**

“We are pleased that GSK are investigating ofatumumab in the treatment of pemphigus vulgaris, a seriously debilitating and sometimes life-threatening autoimmune disease,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

### About the study

The study is double blinded and will include approximately 136 patients with active pemphigus vulgaris who have achieved disease control on a stable dose of steroids prior to randomization. Patients in this study will be randomized equally into one of two arms. Patients will receive either ofatumumab (60 mg) or placebo every 12 weeks for a total of five doses over which time a scheduled gradual steroid reduction will be undertaken. Patients will then be followed for at least 12 weeks longer. The study objectives are to establish the efficacy and safety of subcutaneous ofatumumab in pemphigus vulgaris, based on disease remission. This study is being conducted by GlaxoSmithKline (GSK).

### About pemphigus vulgaris

Pemphigus vulgaris is a rare, chronic skin disorder in which the immune system malfunctions and produces antibodies that attack healthy cells in the skin and mucous membranes. This causes burn-like blisters and sores to appear on the skin or mucous membranes and may lead to secondary skin infections, dehydration, spread of infection through the bloodstream (sepsis) and death. The incidence of pemphigus vulgaris is approximately seven people per million worldwide. The current standard treatment for pemphigus vulgaris is systemic glucocorticoids.

### 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 (Teeling et al 2006). Ofatumumab is being developed under a co-development and commercialization agreement between Genmab and GSK. Under the companies' agreement, GSK is responsible for development of ofatumumab in autoimmune indications and related costs.

In the pivotal trial on which approval for chronic lymphocytic leukemia refractory to fludarabine and alemtuzumab was based (total population n=154), the most common adverse reactions ( $\geq 10\%$ , all grades) to ofatumumab were neutropenia, pneumonia, pyrexia, cough, diarrhea, anemia, fatigue, dyspnoea, rash, nausea, bronchitis, and upper respiratory tract infections. The most common serious adverse reactions were infections (including pneumonia and sepsis), neutropenia, and pyrexia. A total of 108 patients (70%) experienced bacterial, viral, or fungal infections. A total of 45 patients (29%) experienced  $\geq$ Grade 3 infections, of which 19 (12%) were fatal. The proportion of fatal infections in the fludarabine- and alemtuzumab-refractory group was 17%.

Ofatumumab is not approved or licensed anywhere in the world to treat pemphigus vulgaris.

### About Genmab A/S

Genmab is a publicly traded, international biotechnology company specializing in the creation and



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development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company's first marketed antibody, ofatumumab (Arzerra<sup>®</sup>), 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](http://www.genmab.com).

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