



## **GENMAB AND GLAXOSMITHKLINE INITIATE OFATUMUMAB RHEUMATOID ARTHRITIS PHASE III PROGRAM**

*Summary: Genmab and GSK have announced the initiation of the Phase III program with ofatumumab to treat rheumatoid arthritis.*

**Copenhagen, Denmark; November 20, 2007** – Genmab A/S (OMX: GEN) and GlaxoSmithKline (LSE and NYSE: GSK) announced today the initiation of the Phase III program with ofatumumab to treat rheumatoid arthritis (RA). The program will commence with two studies (GEN410/OFA110635 and GEN411/OFA110634) which will be conducted outside the US, in two distinct patient populations. One study will be in patients who have had an inadequate response to methotrexate therapy and the other in patients who had an inadequate response to TNF-alpha antagonist therapy. Further studies to support the program are planned for 2008.

Each study will evaluate the efficacy of ofatumumab in reducing the clinical signs and symptoms in RA patients after a single course of ofatumumab and are comprised of a 24 week double-blind period followed by a 120 week open-label period during which re-treatment will be studied. The primary endpoint in each study is ACR20 at 24 weeks.

“This brings us closer to our goal of broadening the treatment options for patients with this painful and debilitating disease,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab. “From the data to date, we believe that ofatumumab has real potential. Now that Phase 3 studies are underway in multiple indications, we are moving closer to realizing this potential and bringing this important treatment to patients.”

“We are very pleased that our collaboration with Genmab has progressed so that we can now move to the next step of the clinical trial program,” said Dr. Moncef Slaoui, Chairman of Research and Development, GlaxoSmithKline.

Ofatumumab is an investigational, fully human, next generation monoclonal antibody that targets a unique epitope of the CD20 receptor on the surface of B-cells. This epitope is different than other anti-CD20 antibodies currently available or in development.

### **About the trials**

#### **GEN410/OFA110635 - Clinical efficacy and safety of ofatumumab in adult RA patients who had an inadequate response to methotrexate**

A total of approximately 250 patients who had an inadequate response to methotrexate therapy will be enrolled. In the double-blind period, patients will be randomized to receive two 700 mg doses of ofatumumab or placebo two weeks apart in addition to background methotrexate.

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Rescue treatment with nonbiologic disease modifying anti-rheumatic drugs (DMARDs) will be allowed from week 16 in the double-blind period. All patients who complete the double-blind period without receiving rescue treatment will continue into the open-label period of the study. Re-treatment will be studied starting at week 24. Disease status will be measured every 4 weeks during the double-blind period and every 8 weeks during the open-label period.

## **GEN411/OFA110634 - Clinical efficacy and safety of ofatumumab in adult RA patients who have had an inadequate response to TNF-alpha antagonist therapy**

A total of approximately 250 patients who had an inadequate response to TNF-alpha antagonist therapy will be enrolled. In the double-blind period, patients will be randomized to receive two 700 mg doses of ofatumumab or placebo two weeks apart in addition to background methotrexate. Rescue treatment with nonbiologic disease modifying anti-rheumatic drugs (DMARDs) will be allowed from week 16 in the double-blind period. All patients who complete the double-blind period without rescue treatment will continue into the open-label period of the study. Re-treatment will be studied starting at week 24. Disease status will be measured every 4 weeks during the double-blind period and every 8 weeks during the open-label period.

### **About Genmab A/S**

Genmab is a leading international biotechnology company focused on developing fully human antibody therapeutics for unmet medical needs. Using unique, cutting-edge antibody technology, Genmab's world class discovery and development teams have created and developed an extensive pipeline of products for potential treatment of a variety of diseases including cancer and autoimmune disorders. As Genmab advances towards a commercial future, we remain committed to our primary goal of improving 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](http://www.genmab.com).

### **About GlaxoSmithKline**

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For more information, visit GlaxoSmithKline on the World Wide Web at [www.gsk.com](http://www.gsk.com).

### **Genmab forward looking statements**

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## **GlaxoSmithKline Forward-Looking Statements**

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