



## **GENMAB ANNOUNCES RESULTS FROM ZALUTUMUMAB PHASE III STUDY OF REFRACTORY HEAD AND NECK CANCER PATIENTS**

*Summary: Genmab announces top-line results from a study of zalutumumab in refractory head and neck cancer patients who failed platinum based chemotherapy.*

**Copenhagen, Denmark; March 08, 2010** – Genmab A/S (OMX: GEN) announced today top-line results from a zalutumumab Phase III study in patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) who failed standard platinum-based chemotherapy. Median overall survival in patients receiving zalutumumab in combination with best supportive care (BSC) was 6.7 months compared to 5.2 for BSC alone ( $p = 0.0648$ ). Although this represented a 30% improvement (hazard ratio of 1.30), the result was not sufficient to demonstrate a statistically significant difference in overall survival, the primary endpoint of the study. However, patients in the zalutumumab arm did experience a 61% increase in progression free survival compared to patients in the BSC alone arm ( $p=0.0010$ ).

An initial review of the data reveals that 28% of patients randomized to the BSC arm ( $n = 95$ ) and 14% of patients in the zalutumumab arm ( $n = 191$ ) received other anti-cancer therapies not permitted by the protocol. The median time to first use of other anti-cancer therapies was 79 days in the BSC arm compared to 170 days in the zalutumumab arm.

Zalutumumab was generally well tolerated by patients in the study. The safety profile observed for zalutumumab was as expected within this drug class in patients with SCCHN. Adverse events reported more frequently for patients in the zalutumumab plus BSC group were infusion related reactions, skin and nail disorders, electrolyte disturbances (hypomagnesemia and hypokalemia), gastrointestinal disorders (diarrhea grade 1-2), eye disorders, infections and headache. There were no unexpected safety findings. In this dose to rash study, the majority of patients (60%) received the highest dose of zalutumumab, 16 mg/kg.

“The progression free survival data indicates that zalutumumab can provide a benefit to these cancer patients and we will review with our clinical advisors and the regulatory agencies how to best proceed with this product,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab.

The results will be submitted for presentation at the 2010 American Society of Clinical Oncology Annual Meeting in Chicago in June.

### **About the study**

The pivotal, randomized multicenter trial compared zalutumumab in combination with BSC to BSC alone in 286 patients with recurrent or metastatic SCCHN who had previously failed at least one course of standard platinum-based chemotherapy. Patients randomized to zalutumumab in combination with BSC received an initial dose of 8mg/kg of zalutumumab, followed by weekly administrations of individually dose adjusted maintenance therapy of up to 16 mg/kg

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until disease progression. Patients treated with BSC alone were also allowed to receive methotrexate at a maximum weekly dose of 50 mg/m<sup>2</sup>. Disease status was assessed by CT scan or MRI every 8 weeks and response evaluated according to RECIST criteria by an Independent endpoints Review Committee. The primary endpoint in the study was overall survival from randomization until death.

### **About zalutumumab**

Zalutumumab is a novel, investigational, high-affinity, human antibody that targets the Epidermal Growth Factor receptor (EGFr), a molecule overexpressed on the surface of many cancer cells and that is a well validated target. Zalutumumab is in development to treat head and neck cancer and has received Fast Track designation from the FDA for advanced, metastatic and/or unresectable SCCHN that has progressed following standard platinum-based chemotherapy.

Under the FDA Modernization Act of 1997, Fast Track designation means that FDA will take such actions as are appropriate to expedite the development and review of the application for approval of such product. FDA may also evaluate for filing and commence review of portions of an application for approval of a Fast Track product under certain conditions.

### **Conference Call**

Genmab will hold a conference call to discuss today's news on March 08, 2010 at

3:30 PM CET

2:30 PM GMT

9:30 AM EST

The conference call will be held in English.

The dial in numbers are as follows:

+1 877-941-6079 (in the US)

+1 480-629-9779 (outside the US)

Please provide conference ID number 4259908

To listen to a live webcast of the call please visit [www.genmab.com](http://www.genmab.com).

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## 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](http://www.genmab.com).

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Contact: Helle Husted, Vice President, Investor Relations  
T: +45 33 44 77 30; M: +45 25 27 47 13; E: [h.husted@genmab.com](mailto:h.husted@genmab.com)

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