

GENMAB'S HUMAX-EGFR AWARDED FAST TRACK STATUS FROM FDA

In September 2003, Genmab initiated an open label Phase I/II clinical trial using HuMax-EGFr to treat patients suffering from confirmed recurrent or metastatic squamous cell carcinoma of the head and neck who had previously failed standard therapies. Twenty-four patients were included in the initial trial, which was extended in October 2004 to include three additional patients. Patients were divided into six dose groups and received IV infusions of HuMax-EGFr at doses of 0.15, 0.5, 1, 2, 4, or 8 mg/kg. Twenty patients received all five infusions. The primary and secondary endpoints of the study were safety and efficacy of HuMax-EGFr.

Clinical and metabolic response was demonstrated by two types of scanning. Assessed by FDG-PET, which visualizes tumor metabolism, 7 of 18 evaluable patients achieved partial metabolic response (PMR) and 4 had stable metabolic disease (SMD) one week after their fifth and last infusion. In the two highest dose groups, 9 out of 11 patients obtained PMR or SMD.

Clinical response evaluated by computerized tomography (CT scan) supported the positive FDG-PET results. Two of 19 evaluable patients achieved partial response (PR) and 9 patients had stable disease (SD) according to RECIST criteria. The partial response was maintained at week 12 by one of the two patients. The other patient's disease progressed five weeks after the last treatment, but following additional HuMax-EGFr treatment at 8 mg/kg on a compassionate use basis, the patient re-obtained the partial response. In the two highest dose groups 7 out of 10 patients obtained PR or SD.

Results from the trial indicate that HuMax-EGFr is well tolerated by head and neck cancer patients. Furthermore, no patients experienced Dose Limiting Toxicity when treated with the highest dose of 8 mg/kg. The most frequent adverse event was acneiform rash demonstrating biological activity of HuMax-EGFr in 56% of the patients. The occurrence increased with dose, with 10 of 11 patients in the 4 and 8 mg/kg dose groups experiencing rash. Other adverse events included rigors, fatigue, pyrexia, nausea, flushing and increased sweating. One case of grade 3 rash was reported. One patient reported a serious adverse event considered related to treatment with HuMax-EGFr, grade 2 pyrexia, which developed during the first infusion. The patient recovered and completed the study.

About Genmab A/S

Genmab A/S is a biotechnology company that creates and develops human antibodies for the treatment of life-threatening and debilitating diseases. Genmab has numerous products in development to treat cancer, infectious disease, rheumatoid arthritis and other inflammatory conditions, and intends to continue assembling a broad portfolio of new therapeutic products. At present, Genmab has multiple partnerships to gain access to disease targets and develop novel human antibodies including agreements with Roche, Amgen and Serono. A broad alliance provides Genmab with access to Medarex, Inc.'s array of proprietary technologies, including the UltiMab[®] platform for the rapid creation and development of human antibodies to virtually any disease target. Genmab has operations in Copenhagen, Denmark, Utrecht, the Netherlands, and Princeton, New Jersey in the US. For more information about Genmab, visit www.genmab.com.

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