



280 mg) of HuMax-CD4 once weekly for four weeks. After the last treatment, the patients were followed over a period of 11 weeks with the primary endpoint being evaluated at week seven.

Four weeks HuMax-CD4 treatment was safe and well tolerated. PASI was reduced with increased dose levels. Mean PASI was reduced by 12 percent, 14 percent, 16 percent and 24 percent in the active dose groups, respectively. At the highest dose level, 38 percent of the patients obtained more than 25 percent reduction of PASI and half of those patients obtained more than 50 percent reduction of their PASI.

The efficacy results obtained after just four weeks of treatment indicate that longer treatment could lead to even further reduction of PASI, and Genmab therefore plans to proceed to Phase IIb in psoriasis in the second half of 2002.

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

Genmab is a Danish biotechnology company creating and developing fully human antibodies for the treatment of life-threatening and debilitating diseases. Genmab has a number of products in development to treat cancer, rheumatoid arthritis and other inflammatory conditions such as psoriasis. Genmab aims to create a broad portfolio of new therapeutic products based on its research and development. At present, Genmab's commercial opportunities are based upon research in its own laboratories, as well as via alliances with leading international companies, including Roche, Immunex Corporation, Oxford GlycoSciences Ltd., Medarex, Inc., deCODE Genetics, Scancell, Ltd., Sequenom, Inc., Eos Biotechnology Inc., Glauco Proteomics B.V., Bionomics and Paradigm Therapeutics Ltd. Genmab has its headquarters in Copenhagen, Denmark and operations in Utrecht, The Netherlands and Princeton, New Jersey in the US. For more information about Genmab, visit [www.genmab.com](http://www.genmab.com).

### **BACKGROUND**

#### **HuMax-CD4**

HuMax-CD4 is a high affinity fully human antibody that targets the CD4 receptor on T-lymphocytes. These cells are involved in promoting autoimmune disease and an antibody that targets them has the potential to treat several inflammatory diseases including rheumatoid arthritis and psoriasis.

Genmab has conducted HuMax CD4 clinical trials in both rheumatoid arthritis (RA) and psoriasis. A placebo-controlled, multicenter, Phase III clinical trial in rheumatoid arthritis to treat patients who have failed to respond to TNF- $\alpha$  inhibitors and methotrexate is currently ongoing, with results expected next year. The study is expected to treat 402 patients, who will be randomly assigned to one of three treatment groups: placebo, 80mg, or 160mg of HuMax-CD4. These patients will be dosed once at the outset, again at two weeks, then once every four weeks until week 22. The primary clinical endpoint proposed is the mean ACR20 response at 26 weeks.

A Phase II study in a broad RA indication for patients with moderate to severe arthritis despite treatment with methotrexate is also ongoing with results from that study expected this year. A Phase IIb study in psoriasis, which will last approximately a year, is due to start later this year.

#### Fast Track Status

In February, the US Food and Drug Administration (FDA) designated HuMax-CD4 a Fast Track product to treat patients with active rheumatoid arthritis (RA) who have failed to respond to treatment with Methotrexate and TNF- $\alpha$  blocking agents.

Under the FDA Modernization Act of 1997 designation as a Fast Track Product means that the FDA will facilitate the development and expedite the review of a drug if it is intended for the treatment of a serious or life-threatening condition, and it demonstrates the potential to address unmet medical needs for such a condition

#### The PASI scale

PASI is the Psoriasis Area and Severity Index, which is used throughout the dermatology research community as a method of evaluating the effect of treatments. The PASI is scored from 0 – 72. It accounts for the affected area and grades the degree of induration (hardness), erythema (redness) and scaling of the skin lesions. The PASI scale can be used to describe the mean decrease in PASI of the entire patient population or for the percentage of patients that obtain a certain PASI score.

*Except for the historical information presented herein, matters discussed in this press release are forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to differ materially from any future results, performance or achievements expressed or implied by such statements, eg. unforeseen exchange rate and interest rate fluctuations, delayed or unsuccessful development projects.*

*Statements that are not historical facts, including statements preceded by, followed by, or that include the words “believes”; “anticipates”; “plans”; “expects”; “estimates”; or similar statements are forward-looking statements. Genmab is not under an obligation to up-date statements regarding the future following the publication of this release; nor to confirm such statements in relation to actual results, unless this is required by law.*