

Press Release

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Fresenius Biotech obtains reimbursement approval for Removab[®] antibody in Italy

The Italian Medicines Agency, AIFA, has added Fresenius Biotech's antibody Removab[®] to its list of reimbursable medications. As of June 25, 2011, use of Removab[®] for the treatment of malignant ascites in patients with EpCAM-positive carcinomas will be fully reimbursed. Removab[®] is a trifunctional monoclonal antibody approved throughout the European Union. It has been launched in Austria, France, Germany, Scandinavia and the UK.

"The positive decision concerning reimbursement is another step in the successful implementation of our European marketing strategy for Removab[®]," said Dr. Christian Schetter, CEO of Fresenius Biotech. "It enables patients in Italy to benefit from treatment with Removab[®] quickly and without bureaucratic hurdles."

Follow-up results for the pivotal study, recently presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO), showed a statistically significant benefit in overall survival for Removab[®]-treated patients. After six months, nearly 30% of all patients treated with Removab[®] were still alive, which is a fourfold increase compared to the control group (around 7%). In addition, Removab[®]-treated patients were shown to have an improved quality of life.

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About Removab[®] (catumaxomab)

Removab[®], with its trifunctional mode of action, represents the first antibody of a new generation. The therapeutic objective of Removab[®] is to generate a stronger immune response to cancer cells that are the main cause of ascites. Removab[®] binds to three different cell types simultaneously: One arm of the antibody binds to the EpCAM (epithelial cell adhesion molecule) antigen on carcinoma cells, another arm binds to CD3 on T cells. Thirdly, the intact Fc region of Removab[®] binds to Fc γ receptors on accessory cells (such as macrophages, monocytes, dendritic cells and natural killer cells). This simultaneous binding subsequently results in the mutual stimulation and activation of T cells and accessory cells, enabling the generation of a stronger immune response and destruction of cancer cells. Data from animal studies with trifunctional antibodies also suggest a potential long-lasting effect to prevent cancer recurrence. Removab[®] is under further development for new indications. Catumaxomab (Removab[®]) is a trifunctional antibody developed by TRION Pharma GmbH.

Removab[®] has been approved in the European Union since April 2009 for intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible. Fresenius Biotech is responsible for the clinical development and commercialization of Removab[®].

For more information, please visit www.removab.com.

About the pivotal study

The study involved 258 patients with malignant ascites due to various carcinomas. Of those, 129 suffered from ovarian cancer, while another 129 had other types of cancer. Patients received paracentesis followed by four intraperitoneal infusions of Removab[®], or paracentesis alone (control group). Details of the study results are published by Heiss et al, *Int J Cancer* 2010;127:2209–21

About epithelial cell-adhesion molecule (EpCAM)

EpCAM is a tumor-associated antigen expressed on the vast majority of epithelial tumors. EpCAM is expressed on tumor cells in the ascites fluid of patients with EpCAM-positive tumors.

About malignant ascites

Malignant ascites can be caused by various kinds of tumors. The peritoneal spread of tumor cells leads to an accumulation of fluid in the peritoneal cavity and is associated with an unfavorable prognosis for the patient. The most common method of treatment is paracentesis, which generally must be repeated at intervals

of one to two weeks and can lead to complications such as infections or elevated losses of fluids and proteins. Removab® destroys the peritoneal cancer cells and thus directly attacks the cause of malignant ascites.

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Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2010, Group sales were approximately €16.0 billion. On March 31, 2011, the Fresenius Group had 140,111 employees worldwide. For more information, visit the company's website at www.fresenius.com.

Fresenius Biotech, a company of the Fresenius health care group, is focused on the development, marketing and commercialization of biopharmaceuticals in the fields of oncology and transplantation medicine. Fresenius Biotech is a German company headquartered in Munich. For more information, please visit www.fresenius-biotech.com.

Removab® is a registered trademark of Fresenius Biotech.

This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g., changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

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