FRESENIUS

Press Release

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Fresenius Biotech's Removab® receives approval for a shorter infusion time in treating malignant ascites – one-year survival rate in Removab®-treated patients is more than four times higher

The European Commission has broadened the existing approval of Fresenius Biotech's antibody Removab® (catumaxomab) to treat malignant ascites by allowing a shorter infusion time. The infusion time for Removab® can now be halved, from six to three hours. Moreover, the approval allows marketing of follow-up results for the pivotal study in patients with malignant ascites showing that the one-year survival rate in Removab®-treated patients was more than four times higher than in the control group (11.4% Removab group vs. 2.6% control group). The summary of product characteristics for Removab® will include the overall survival data from the pivotal study with immediate effect. The broadened approval follows on the recommendation of the Committee for Medicinal Products for Human Use (CHMP), part of the European Medicines Agency (EMA). It is valid in all EU countries and also confirms the safety profile of the trifunctional antibody.

The European Commission's decision is based on the results of an analysis of pooled safety data. In clinical studies, Removab® was administered intraperitoneally as three or six-hour infusions. The safety profiles for both administrations were comparable.

Thanks to the shortened infusion time, Removab® will be easier to use in out-patient settings. "Treatment options for patients with malignant ascites must not only be effective, but also minimize the burden for the patient," said Prof. Dr. Barbara Schmalfeldt from the obstetrics and gynecology department at Technical University of

Munich. “A shorter infusion time means patients spend less time at their physician’s office or day clinic. The new application time for Removab® addresses this frequent patient request. It also makes applications in day-to-day practice much easier and more efficient.”

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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 Fcγ 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 June 30, 2011, the Fresenius Group had 142.933 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.

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