FRESENIUS

Investor News

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EMEA-Committee for Medicinal Products for Human Use issues positive opinion for Removab® (catumaxomab) for the treatment of malignant ascites

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) today issued a positive opinion recommending approval of Removab for the intraperitoneal treatment of malignant ascites.

The approval by the European Commission (EC) is expected within a few months. The decision, which is usually based on the CHMP opinion, will apply to all EU member states. Removab would be the first drug worldwide with a regulatory label for the treatment of malignant ascites. Fresenius Biotech is prepared to launch Removab upon approval.

The CHMP opinion is based on the results of one large international phase II/III pivotal study with the primary endpoint of puncture-free survival*. The study demonstrated that patients receiving Removab experienced a four-fold increase in puncture-free survival over a therapy consisting of puncture alone. These data were presented at the 2008 Annual ASCO Meeting in Chicago, Illinois.

"The positive opinion is important news for all cancer patients diagnosed with malignant ascites and we look forward to filling a high unmet medical need with Removab" says Ulf Mark Schneider, Chairman of the Management Board of Fresenius SE. "The launch of Removab is a significant milestone for Fresenius Biotech as it progresses from the development to the successful commercialization of biopharmaceutical products."

BACKGROUND INFORMATION:

*About the Pivotal Study

The study involved 258 patients with malignant ascites due to carcinomas. Of those, 129 suffered from ovarian cancer while another 129 had non-ovarian cancers. Patients received both puncture (paracentesis) and four intraperitoneal infusions of Removab within 11 days, or paracentesis alone (control group).
The trial met its primary endpoint with high statistical significance. Patients treated with Removab showed a median puncture-free survival (primary endpoint) of 46 days compared with 11 days in the control group ($p < 0.0001$) (Hazard Ratio: 0.254). Puncture-free survival was defined as the period between the last infusion and the first subsequent necessary puncture or death, whichever occurred first. The median puncture-free time – a secondary endpoint which did not include the data from patients who died before the next ascites puncture was due – was 77 days versus 13 days ($p < 0.0001$).

The most common side effects observed during the trial, such as fever, nausea and vomiting were all due to Removab's postulated mode of action.
These side effects were predictable, limited, manageable and mostly fully transient.

Malignant Ascites

Malignant ascites can be caused by different carcinomas. Abdominal spread of cancer cells leads to an accumulation of fluid in the abdominal cavity and is associated with a poor prognosis. The most commonly used treatment of malignant ascites is puncture (paracentesis), which has to be carried out on average every one to two weeks and can lead to complications such as infection and fluid or protein deprivation. The trifunctional antibody Removab is known to kill cancer cells in the peritoneal cavity and therefore attacks the primary cause of ascites formation.

Trifunctional Antibody 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 reaction against cancer cells. Removab binds to three different cell types simultaneously: One arm of the antibody recognizes and binds to T cells, the other arm binds EpCAM (epithelial cell adhesion molecule) that is expressed in many types of carcinomas. In addition, immune effector cells with Fc receptors (such as macrophages, monocytes, dendritic cells and natural killer cells) bind to the Fc region of Removab. This simultaneous binding subsequently results in the co-stimulation and activation of T cells and accessory cells, enabling the generation of a strong immune response against cancer cells.
Preclinical data for trifunctional antibodies also suggest a potential long-lasting effect to prevent cancer recurrence. Removab is further developed in various indications (e.g. gastric and ovarian cancer) addressing the underlying cancer.
Catumaxomab is a trifunctional antibody developed by TRION Pharma GmbH.

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Fresenius is a German health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2007, group sales were approx. € 11.4 billion. On September 30, 2008 the Fresenius Group had 121,288 employees worldwide.

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 with headquarters in Munich. For further information please visit www.fresenius-biotech.com.

TRION Pharma is a biopharmaceutical company developing trifunctional antibodies in collaboration with Fresenius Biotech. The trifunctional antibodies are produced at TRION's site in Munich, Germany, and are based on a proprietary platform technology for which TRION has secured IP around the world. For further information please visit www.trionpharma.com.

For more information visit the Company's website at www.fresenius.com.