



P R E S S R E L E A S E

December 18, 2006
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Phase II/III pivotal study with trifunctional antibody removab[®] shows encouraging results in malignant ascites

Fresenius today announced encouraging results from a phase II/III pivotal study on malignant ascites in patients with ovarian cancer using the trifunctional antibody removab[®] (catumaxomab). The antibody showed a clear advantage over a therapy with puncture alone. The median puncture-free survival period (primary endpoint) in the group of patients treated with removab[®] was significantly longer compared to the control group and clinically relevant. The median puncture-free survival was 52 days in the removab[®] group versus 11 days in the control group ($p < 0.0001$).

Positive results were also achieved with regard to key secondary endpoints. The median time to the first therapeutic puncture was 71 days (control group: 11 days; $p < 0.0001$). In contrast to the primary endpoint, patients who died before the next puncture were not included in this metric. Also, the EpCAM-positive tumor cell concentration in the ascites fluid decreased significantly in patients treated with removab[®] ($p < 0.0009$). At the same time, an increase in CD45-positive leukocytes was seen. Both results indicate a direct anti-tumor effect of the trifunctional antibody.

Moreover, removab[®] showed a very good safety profile. Side effects were mild to moderate with fever, nausea and vomiting being the most common. Pathologic

increases of liver parameters and undesirable changes in white blood cell counts were also mild to moderate, transient and without clinical relevance.

“To date, there are only limited therapy options for ovarian cancer patients with malignant ascites. Our data indicate that removab[®] could become an important new therapy option for this disease. The positive results of the phase I/II study have been fully confirmed by this pivotal phase II/III trial,” said Dr. Thomas Gottwald, President Fresenius Biotech.

The results of this two-arm, randomized, open-label study include treatment data of 129 ovarian cancer patients with ascites. The removab[®] arm included 85 patients, of which 73 received all four doses of 10, 20, 50 und 150 µg each. The intraperitoneal infusions were administered over a six-hour period in intervals of three to four days.

Data on overall survival in connection with the study are expected in the first half of 2007 due to the longer follow-up period associated with this secondary endpoint. Market launch of removab[®] is expected in 2008.

The current phase II/III study with the trifunctional antibody removab[®] included a total of 257 patients. The results of the second group (128 patients) with tumor diseases other than ovarian cancer (e.g. gastric cancer) are expected for the first half of 2007.

Puncture-free survival period

Period between the last infusion (control group: day of the puncture) and the first subsequent necessary puncture or death, which ever occurs first.

Trifunctional Antibodies

Trifunctional antibodies are developed by Fresenius Biotech in cooperation with TRION Pharma. Trifunctional antibodies are proteins that bring together cancer

cells with two different cell types of the immune system: T-cells and accessory cells (e.g., natural killer cells, macrophages). This mode of action of the trifunctional antibody is the basis for an immune response against the tumor.

Fresenius Biotech is a company of the Fresenius health care group, focused on the development and marketing of biopharmaceuticals in the fields of oncology, immunology and regenerative medicine. Additional information is available on the Internet at www.fresenius-biotech.de.

Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and the ambulatory medical care of patients. In 2006 group sales are expected to increase to more than € 10.7 billion. On September 30, 2006 the Fresenius Group had 104,179 employees worldwide. Additional information is available on the Internet at fresenius-ag.com

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.