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Fresenius Investor News

Phase II/III pivotal study with trifunctional antibody removab® shows encouraging results in malignant ascites from various cancers

Fresenius today announced encouraging results in the non-ovarian cancer patient stratum of a phase II/III pivotal study on malignant ascites using the trifunctional antibody removab® (catumaxomab). After positive results in the treatment of patients with ascites from ovarian cancer (see Investor News December 18, 2006 for ovarian stratum), the antibody again showed a clear advantage over a therapy with puncture alone. The median puncture-free survival period (primary endpoint) in the patient group treated with removab® was significantly longer compared to the control group and clinically relevant. The median puncture-free survival was 37 days in the removab® group versus 14 days in the control group ($p < 0.0001$).

In the subgroup of patients with ascites from gastric cancer (51 % of all non-ovarian cancer patients) the difference was even more marked with a median puncture-free survival of 44 days in the removab® group versus 15 days in the control group ($p<0.0001$). All other patients (10 % breast, 7 % pancreatic, 6 % colorectal cancer, 26 % others) had a median puncture-free survival of 30 days (removab®) versus 9 days in the control group ($p<0.0003$). On a pooled basis for both strata (ovarian and non-ovarian cancers) the median puncture-free survival was 46 days in the removab® group versus 11 days in the control group ($p<0001$).

Positive results were also achieved in key secondary endpoints. Of special importance was the length of time between treatment and first therapeutic puncture (median time to the first therapeutic puncture). In contrast to the primary endpoint, patients who died before the next

puncture were not included in this metric. As a result, this secondary endpoint is not affected by the prognosis of these patients at the onset of ascites. The median time to the first therapeutic puncture for all non-ovarian cancers was 80 days (control group: 15 days; p< 0.0001). Patients with gastric cancer benefited especially from the treatment. Median time to the first therapeutic puncture was 118 days in the removab® group versus 15 days in the control group (p< 0.0001). For all other patients the median time to the first therapeutic puncture in the removab® group was 69 versus 15 days in the control group (p< 0.0001). On a pooled basis for both strata (ovarian and non-ovarian cancers) the median time to the first therapeutic puncture was 77 days in the treatment group versus 13 days in the control group (p< 0.0001). In addition, the EpCAM-positive tumor cell concentration in the ascites fluid decreased in patients treated with removab®. At the same time, an increase in CD45-positive leukocytes was seen. Both results indicate a direct anti-tumor effect of the trifunctional antibody.

Removab® showed a very good safety profile in this stratum. This is particularly important as malignant ascites occurs at a very late stage in patients with non-ovarian cancers. Drug-related adverse events due to cytokine release were mild to moderate and mostly fully reversible, 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 mostly without clinical relevance.

“These results continue to support the potential of removab. They demonstrate the significant benefit for ascites patients due to non-ovarian cancers even though they have a worse prognosis compared to ovarian cancer. This indicates that removab® could also play an important role in the treatment of ascites for all underlying non-ovarian cancers,” said Dr. Thomas Gottwald, President Fresenius Biotech.

The phase II/III pivotal trial with the trifunctional antibody removab® included a total of 258 patients divided in two strata: ovarian cancer (129 patients) and non-ovarian cancers (129 patients). Based on a 2:1 randomization ratio, the removab® arm in the non-ovarian stratum included 85 patients, of which 62 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.

Non-ovarian cancer patients account for about 80 % of all malignant ascites cases. The encouraging results of this study signifcantly increase the number of patients that is potentially eligible for the removab® treatment.

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

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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.

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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.