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Fresenius Investor News

ASCO-Meeting: Fresenius Biotech presents clinical trial results of new antibodies at the world's largest cancer convention

Fresenius Biotech successfully completed two Phase I studies evaluating trifunctional antibodies in the treatment of breast cancer and peritoneal carcinomatosis. The results of these studies were presented by investigators from the participating universities at the American Society of Clinical Oncology (ASCO) Annual Meeting in Orlando, Florida.

Encouraging results were achieved with the trifunctional antibody rexomun® (WHO INN: ertumaxomab), which was evaluated in a clinical trial for the first time. In this multi-center Phase I study including patients with metastastic breast cancer, rexomun® (ertumaxomab) proved to be safe and tolerable. Seventeen patients were involved in the study and received three intravenous doses of the antibody within a two-week period. The maximum tolerated doses for the first, second and third application were found at 10, 100 and 100 micrograms. Side effects were mild to moderate and transient with fever, chills, headache and nausea being the most common. In five out of 15 evaluable patients the tumor responded to the treatment leading to stable disease or remission. One patient had a complete remission that lasted for seven months, two patients had a partial remission and two patients had stable disease. One patient with partial remission and two patients with stable disease received concomitant or subsequent hormone therapy. "These data strongly encourage us to proceed into phase II," said Dr. Thomas Gottwald, President of Fresenius Biotech. A Phase II study evaluating the efficacy of rexomun® (ertumaxomab) in breast cancer is in preparation and will start by the end of 2005.

In the second multi-center Phase I study presented at the ASCO convention, the trifunctional antibody removab® (INN: catumaxomab) proved to be safe and tolerable in the treatment of peritoneal carcinomatosis. A total of 17 patients were included. In 16 patients the peritoneal carcinomatosis was caused by cancer of the stomach or the colon. In one patient, the primary tumor could

not be located. Four increasing doses of removab® (catumaxomab) were injected into the peritoneal cavity of the patients over a 10-day period. The maximum tolerated doses were found at 10, 20, 50 and 200 micrograms in the first, second, third and fourth infusion. Side effects were mild to moderate and transient with nausea, abdominal pain and fever being the most common. Irrigation of the peritoneal cavity was possible in eight patients before and after the treatment to determine the effect on the number of detected tumor cells, which decreased in seven out of these eight patients after treatment.

The average life expectancy of patients with peritoneal carcinomatosis normally ranges from three to six months. To date, 14 months after the start of the study, 7 out of 17 patients are still alive. Follow up showed survival of about 9 months after the start of treatment. Complete remission was achieved in one patient which continues after 14 months. "Again, like in the previous study on the trial on malignant ascites due to ovarian cancer, we have observed first signs of efficacy at an early stage of the clinical development," explained Dr. Thomas Gottwald. A pilot study is now evaluating the best mode of application of removab® (catumaxomab) in gastric cancer. A Phase II study on gastric cancer is expected to start by the end of 2005.

The trifunctional antibody removab® (catumaxumab) is also currently being evaluated in a Phase IIa trial in the treatment of ovarian cancer and in a Phase II/III pivotal trial in the treatment of malignant ascites. The results of these studies should be available during 2006.

The antibodies rexomun® (ertumaxomab) and removab® (catumaxomab) were developed and produced by Fresenius Biotech's partner TRION Pharma, a Munich-based biotech company. These novel antibodies have a unique mode of action. Trifunctional antibodies selectively bring together cancer cells and two different immuno-competent cell types thus prompting the destruction of the tumor cells. In addition, trial results indicate that these antibodies prime the immune system with the potential for long lasting immunity against the tumor.

Clinical studies: Phase I studies evaluate dose, safety and tolerability while Phase II clinical trials investigate the efficacy of new drugs.

INN: International Nonproprietary Name; Each INN is selected by the WHO, is a unique name that is globally recognized and is public property.