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Fresenius Investor News

Fresenius Biotech Reports Encouraging Phase IIa Results for its Trifunctional Antibody Removab in Ovarian Cancer Patients: Higher Dose Regimen Improves Tumor Response Without Affecting Good Tolerability

Fresenius Biotech today announced encouraging results from a Phase IIa study with the trifunctional antibody removab® (INN: catumaxomab) in the treatment of ovarian cancer patients. This European multi-center study was designed to assess the relative safety and efficacy of two different dose regimens, and included 44 patients with advanced ovarian cancer that were resistant to platinum and paclitaxel standard chemotherapy following surgery or had relapsed within six months of treatment. Both dose regimens were associated with the same mild to moderate toxicity profile, and the high dose treatment group showed a better tumor response. Currently, there are no other generally accepted treatment options for this patient population.

Patients were given four doses of removab® via intraperitoneal administration over a period of ten days. The primary objective of the study was to determine whether application of a constant low dose (10-10-10-10 µg) or an escalated dose (10-20-50-100 µg) yielded a difference in either tolerability or response rate.

The study yielded two key findings:

- The antibody was well tolerated even at higher doses. Only moderate and temporary side effects were observed at both dose regimens, including fever, nausea and vomiting, and local skin reaction.
- The higher dose regimen yielded a clearly better anti-tumor efficacy, with one complete response (out of 22 patients) in this group. Four instances of stable disease were observed in the higher dose regimen. Two instances of stable disease were observed with the constant low dose regimen.

Based on the encouraging results of this Phase IIa study, Fresenius Biotech is planning to start a European Phase II study in the second half of 2006 to investigate the efficacy of removab® in the treatment of ovarian cancer. In this study the additional benefit of removab® in conjunction with surgery and standard chemotherapy will be investigated. As of today, the study will be designed to treat about 40 patients in earlier stages of the disease. These patients will receive four postoperative doses, as in the Phase IIa study, and an additional dose immediately after the tumor mass has been resected (R0 and RI resection).

Background information

Trifunctional antibodies: The trifunctional antibodies developed by Fresenius Biotech's partner TRION Pharma are proteins that join cancer cells with two different defensive cells from the body's own immune system: T-Cells and accessory cells. This initiates an especially efficient destruction of tumor cells.

Study phases: The goal of a Phase I study is to determine potential dosages and side effects while a Phase II investigates the effectiveness and safety of a medication using a low number of patients. A Phase IIa study is used to compare the safety and efficacy of various dosages. A Phase III study evaluates the effectiveness of a drug using a larger number of patients. The drug is also compared with standard treatments and a risk analysis is performed.

Ovarian cancer affects an average of 12.8 of 100,000 women and is the sixth most common cancer among women. In 2002, the World Health Organization registered more than 200,000 new cases worldwide and more than 120,000 patients died of the disease that year. Because there are no early warning signs for ovarian cancer, three-fourths of all cases are first diagnosed at an advanced stage. Despite improvements in chemotherapy with platinum, two-thirds of all patients fail to react to this treatment or relapse. This results in a relatively low survival rate with just 30 to 40 percent of ovarian cancer patients surviving the first five years.