Fresenius
The Health Care Group

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Fresenius Investor News

Phase I/II study completed successfully: New antibody to treat ovarian cancer patients with symptomatic ascites (fluid accumulation in the abdominal cavity) shown to be well tolerated

The Fresenius Health Care Group has successfully completed a phase I/II study with the new trifunctional antibody removab®. This antibody was used to treat late-stage ovarian cancer patients with symptomatic ascites, which is an accumulation of fluid in the abdominal cavity caused by tumor cells. The study is the world's first completed trial with a trifunctional antibody.

This phase I/II study was designed to identify potential side effects associated with removab® therapy, to evaluate potential dosing schedules and to obtain first indications regarding efficacy. Results of the completed study demonstrate that the antibody is well tolerated at various doses. Four or five very small doses of the antibody were infused into the patient's abdominal cavity over a period of less than two weeks. The most frequent side effects observed in the trial were increased temperature and nausea. In addition, initial indications observed from this study suggest that removab® is efficacious in killing tumor cells in the ascites fluid and thus prevents the re-accumulation of fluid. All patients responded to the therapy. 22 of 23 patients who previously suffered from ascites were ascites-free on day 37, the last day of the study. A significant decrease in the number of tumor cells detected in the ascites fluid was observed in all patients in the study. The average number of tumor cells

detected per one million cells in ascites fluid decreased from 540,000 prior to treatment to 39 following the last infusion.

The head of the clinical trial, Prof. Dr. Rainer Kimmig from The University Hospital of Essen, presented the results of the study yesterday (22.9.) at the European Cancer Conference (ECCO) in Copenhagen. In total, 23 ovarian cancer patients with malignant ascites were treated. Prior to entering the Phase I/II study, all patients had suffered one or more relapses following surgical tumor resection, with consequent tumor development in the abdominal cavity. In most cases, patients had previously undergone one or more courses of chemotherapy. The adhesion molecule EpCAM, the target of the removab® antibody, had been detected on the surface of tumor cells in the abdominal cavity fluid of all patients participating in the study. Production of EpCAM, which is also present in healthy cells, is significantly increased in approximately 90 per cent of ovarian cancer patients. EpCAM can thus be targeted for tumor cell recognition and induction of tumor-specific killing.

Due to the encouraging results of the phase I/II study, Fresenius Biotech is planning to launch two further studies in December 2003 and February 2004. The first study is designed to test the efficacy of the antibody with regard to ovarian cancer metastases and thus increase life expectancy. The second trial will investigate the efficacy of the antibody against ascites in other malignancies.

Assuming successful completion of clinical trials and following consultation with regulatory officials, Fresenius plans potential market launch of removab® in Europe in 2007.

Background information

Trifunctional antibodies

The trifunctional antibodies developed and produced by TRION Pharma, a Fresenius partner, are proteins which specifically bind cancer cells to two different immune cells of the immune system, T-cells and macrophages, thus triggering a process that effectively kills tumor cells. The goal of scientists and clinicians is to eradicate those tumor cells that may still be present in the body following surgical resection of the tumor, preventing the development of ascites or metastases and extending patient survival.

Ascites

Ascites, an accumulation of body fluid in the abdominal cavity, is painful and severely impairs a patient's quality of life. Up to 89 per cent of final-stage ovarian cancer patients develop ascites. Existing palliative treatment methods are unsatisfactory: Puncturing the abdominal cavity (paracentesis) and draining the fluid provides rapid but short-lived relief to the patients. In addition, paracentesis causes patients to lose valuable endogenous proteins. Another approach is to infuse chemotherapeutic agents into the abdominal cavity. This method is not generally accepted due to the severe side effects and limited clinical benefits.

Phase I/II Studies

Phase I studies are aimed at determining the dose and side effects, while phase II studies test the efficacy of the drug treatment.

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Fresenius Biotech GmbH is a company of the Fresenius Group, focused on the development and marketing of biopharmaceuticals in the fields of oncology, immunology and regenerative medicine.