Fresenius
health care worldwide

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Fresenius Investor News

European Commission grants Orphan Drug Designation for the removab® antibody to treat gastric cancer

Fresenius Biotech today announced that the European Commission has granted Orphan Drug Designation for the removab® (catumaxomab) trifunctional antibody to treat gastric cancer. The Orphan Drug Designation entitles Fresenius to up to 10 years market exclusivity in the EU upon marketing approval.

Results from an ongoing phase II study using catumaxomab in about 50 gastric-cancer patients are expected in the second half of 2007. A previous phase I study in patients with advanced peritoneal carcinomatosis (spread and growth of tumor cells in the abdominal cavity) also included patients with gastric cancer and was completed successfully.

Gastric cancer affects an average of three out of 10,000 people in the EU and accounts for about twelve percent of cancer fatalities around the world, making it the second-leading cause of death caused by cancer. Despite medical advances, gastric cancer patients continue to face a low survival rate. Most patients are first diagnosed at an advanced stage because early symptoms are missing or are very unspecific. In addition, many patients face early relapse after surgical resection of the tumor and subsequent chemotherapy, making new, innovative treatments for gastric cancer a high medical need.

Orphan Drug

The EU grants the Orphan Drug Designation to medicinal products used for rare, life-threatening or chronic diseases that affect no more than five in every 10,000 people in the EU and for which no sufficient effective treatment exists. The European Medicines Agency, the EU pharmaceutical regulatory body, supports businesses that research, develop and market such medicines during the development and regulatory approval process.