

Press Release

Positive CHMP Opinion for Removab[®] Validates TRION's Triomab[®] Technology

February 19, 2009 – Munich, Germany – TRION Pharma GmbH today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of its trifunctional antibody Removab[®] for the intraperitoneal treatment of malignant ascites.

This recommendation is an important step towards receiving the final decision and marketing authorization by the European Commission (EC). The Marketing Authorisation Application was filed by TRION's partner Fresenius Biotech in December 2007.

According to the CHMP, Removab[®] meets all quality, safety and efficacy requirements. The scientific committee came to the conclusion that Removab[®] has a positive risk-benefit balance in favor of patients and therefore should reach the European marketplace. The phase II/III study, conducted by Fresenius Biotech, showed consistently favorable data for primary and secondary endpoints. Pivotal results were communicated by Fresenius today.

Catumaxomab is the most advanced drug candidate of the Triomab[®] family, a novel class of trifunctional antibodies developed and manufactured by TRION Pharma. Alongside catumaxomab, there are currently three more Triomab[®] molecules in pre-clinical or clinical development for various cancer indications. "The positive assessment of catumaxomab by the CHMP confirms and validates our Triomab[®] technology as such", said Horst Lindhofer, CEO of TRION Pharma. He founded TRION Pharma 11 years ago with the idea of developing this unique antibody format. Lindhofer: "We are confident that catumaxomab will soon be the first approved bispecific, trifunctional antibody worldwide."

Triomab[®] trifunctional antibodies bind to cancer-associated surface antigens and recruit both T-cells as well as accessory cells from the human immune system. This unique mode of action makes them at least 1,000-fold more effective in destroying cancer cells than conventional monospecific antibodies. Whereas these are applied in doses of milligrams or grams, Triomab[®] antibodies work in the range of micrograms and can thus be produced in much smaller facilities. "Our in-house production capacities will be able to supply Removab[®] for the world market, including potential future indications", said Lindhofer. While Fresenius Biotech will market Removab[®], TRION Pharma is responsible for manufacturing the antibody.

Removab[®]'s target, EpCAM (Epithelial Cell Adhesion Molecule), is expressed on almost all carcinomas including the most frequent forms of cancer. Once approved, Removab[®] will be the only anti-EpCAM antibody on the market. Lindhofer comments: "Together with our partner, we intend to exploit the full therapeutic potential of Removab[®]. What we learned from pivotal study data is that ascites patients benefit from Removab[®] therapy independent of the underlying type of tumor. Thus, we are exploring further indications in which patients will benefit from catumaxomab therapy."

#

Notes to Editors

EpCAM

EpCAM or epithelial cell adhesion molecule is a pan-epithelial differentiation antigen that is expressed on almost all carcinomas, such as breast, lung, colorectal, gastric, prostate and ovarian cancer. Currently, there is no approved anti-EpCAM antibody available.

Triomab[®]: Trifunctional antibodies

The trifunctional antibody catumaxomab is a member of the Triomab[®] family. Triomab[®] antibodies bind to cancer-specific surface antigens and recruit both T-cells as well as accessory cells, such as macrophages, dendritic cells and natural killer cells, to the tumor site. As a result, they provide for a new quality of cancer cell killing, activating both arms of the immune system – the adaptive one with cytotoxic T cells as effectors and the innate one including accessory effector cells. Triomab[®] antibodies are therefore very effective in destroying cancer cells and show a therapeutic effect at very low doses. Triomab[®] antibodies are a development of TRION Pharma GmbH.

TRION Pharma GmbH is a biopharmaceutical company developing trifunctional antibodies (Triomab[®]) in collaboration with Fresenius Biotech. The trifunctional antibodies are produced at TRION's site in Munich, Germany, and are based on a proprietary platform technology for which TRION has secured IP rights around the world. For more information please visit the company's website at www.trionpharma.com.

Fresenius Biotech GmbH, a company of the Fresenius health care group, is focused on the development, marketing and commercialization of biopharmaceuticals in the fields of oncology and transplantation medicine. Fresenius Biotech is a German company with headquarters in Munich. For further information please visit www.fresenius-biotech.com.

Fresenius SE is a German health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2007, group sales were approx. € 11.4 billion. On September 30, 2008 the Fresenius Group had 121,288 employees worldwide. For further information please visit www.fresenius.com.

Contact

Dr Dirk Pelster
Chief Operating Officer (COO)
TRION Pharma GmbH
Frankfurter Ring 193a
D - 80807 Munich
Germany

Tel: +49-89-3242-66-111
Fax: +49-89-3242-66-599
dirk.pelster@trionpharma.de