

## Investor News

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### **Fresenius Biotech applies for the marketing authorization of the trifunctional antibody Removab<sup>®</sup> for the treatment of malignant ascites**

Fresenius Biotech has dispatched the marketing authorization application for the trifunctional antibody Removab (INN: catumaxomab) in patients with malignant ascites to the European Medicines Agency (EMA) as planned. The company applies for the EU authorization of Removab for the intraperitoneal treatment of malignant ascites in patients with epithelial cancers where no standard therapy is available or no longer feasible. The results of the phase II/III pivotal study announced in December 2006 as well as in March and July 2007 are an essential part of the marketing authorization application. In addition to the clinical results, the application contains preclinical data as well as production and product quality information. The scientific assessment of the marketing authorization application will start in early 2008 after the completion of the validation by EMA.

Dr. Ulf M. Schneider, Chairman of the Management Board of Fresenius SE, commented: "The marketing authorization application for our Removab antibody is an important milestone for Fresenius Biotech. The results of the phase II/III pivotal study show clear benefits for patients treated with Removab. We believe that Removab could become a new therapy option for malignant ascites. We are encouraged to continue our Removab clinical trial program and will focus on applications in solid tumors."

### **Trifunctional Antibodies**

Trifunctional antibodies are proteins that activate different cell types of the immune system simultaneously and direct these to the tumor cells by a targeted approach. Trifunctional antibodies therefore are very effective in destroying cancer cells and show a therapeutic effect even at very low doses. They are being developed by TRION Pharma GmbH.

### **Mode of action of trifunctional antibody removab (catumaxomab)**

The therapeutic objective of trifunctional antibodies is to generate a stronger immune reaction against tumor cells. removab has two different antigen binding sites: While one arm of the antibody recognizes and binds to T-cells, the other arm binds EpCAM (epithelial cell adhesion molecule) that is overexpressed in many types of epithelial cancers. Immune effector cells with Fc receptors (macrophages, monocytes, dendritic cells and natural killer cells) can also bind the Fc region of intact trifunctional antibodies. This simultaneous binding subsequently results in the costimulation and activation of T-cells and accessory cells, enabling the generation of a strong immune response against tumor cells. Preclinical data also suggest a potential long-lasting effect to prevent cancer recurrence. Apart from removab two other trifunctional antibodies targeting other cancer antigens are currently undergoing clinical development.

### **About Fresenius Biotech**

Fresenius Biotech is a company within the Fresenius health care group and is focused on the development and marketing of biopharmaceuticals in the fields of oncology, immunology and regenerative medicine. For further information please visit [www.fresenius-biotech.de](http://www.fresenius-biotech.de).

### **About Fresenius**

Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2006, group sales were about € 10.8 billion. On September 30, 2007 the Fresenius Group had 110,379 employees worldwide. For further information please visit [www.fresenius.com](http://www.fresenius.com).

## **About TRION Pharma**

TRION Pharma is a biopharmaceutical company that develops and produces trifunctional antibodies based on a globally patented technology platform together with Fresenius Biotech in Munich. For further information please visit [www.trionpharma.de](http://www.trionpharma.de).

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## **Glossary**

**Epithelial tumors:** tumors that result from degenerated cells of epithelial origin.

This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

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