FRESENIUS BIOTECH

Press Release

Matthias Link
Corporate Communications

Fresenius SE & Co. KGaA
Else-Kröner-Strasse 1
61352 Bad Homburg
Germany
T +49 6172 608-2872
F +49 6172 608-2294
matthias.link@fresenius.com
www.fresenius-biotech.com
www.removab.com

June 7, 2011

ASCO 2011: Fresenius Biotech presents new data for the trifunctional antibody Removab® – benefit in overall survival of cancer patients demonstrated

At the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago (June 3-7, 2011), Fresenius Biotech presented new data on the trifunctional antibody Removab® with 11 contributions.

Significant overall survival benefit in patients with higher relative lymphocyte count

Follow-up results for the pivotal study in patients with malignant ascites show a statistically significant benefit in overall survival for Removab®-treated patients (p=0.0219, HR=0.649). The six-month survival rate in Removab®-treated patients was more than four times higher compared to control patients (28.9% vs. 6.7%). A higher baseline-relative lymphocyte count (RLC) had a significant impact on overall survival. In patients with a RLC >13%, the six-month survival rate with Removab® was more than seven times higher than in control patients (37.0% vs. 5.2%), leading to a mean overall survival benefit of 131 days (p=0.0072, HR=0.518). The RLC was previously identified as a biomarker in an independent hypothesis-generating study.

Removab® improves quality of life in patients with malignant ascites

In addition to improving overall survival, Removab®-treated patients were shown to have an improved quality of life (QoL). Analysis of pivotal trial data using the EORTC QLQ-C30 questionnaire showed a significantly higher percentage of patients

with improvement in QoL scores at day 30. This effect appeared consistently across multiple scores. While nearly all (97%) patients treated with Removab® at least maintained their QoL level ("Global QoL score"), 30% of patients in the control group had a rapid deterioration in QoL within the first 30 days.

Integrated safety analysis supports shorter infusion time

A shorter infusion time of 3 hours for Removab® is supported by new results from an integrated safety analysis. Based on this analysis, the safety profile of Removab® after a more tolerable and convenient 3-hour infusion was largely comparable to the currently approved 6-hour infusion time.

###

About Removab® (catumaxomab)

Removab®, with its trifunctional mode of action, represents the first antibody of a new generation. The therapeutic objective of Removab® is to generate a stronger immune response to cancer cells that are the main cause of ascites. Removab® binds to three different cell types simultaneously: One arm of the antibody binds to the EpCAM (epithelial cell adhesion molecule) antigen on carcinoma cells, another arm binds to CD3 on T cells. Thirdly, the intact Fc region of Removab® binds to Fcγ receptors on accessory cells (such as macrophages, monocytes, dendritic cells and natural killer cells). This simultaneous binding subsequently results in the mutual stimulation and activation of T cells and accessory cells, enabling the generation of a stronger immune response and destruction of cancer cells. Data from animal studies with trifunctional antibodies also suggest a potential long-lasting effect to prevent cancer recurrence. Removab® is under further development for new indications. Catumaxomab (Removab®) is a trifunctional antibody developed by TRION Pharma GmbH.

Removab® has been approved in the European Union since April 2009 for intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible. Fresenius Biotech is responsible for the clinical development and commercialization of Removab®.

For more information, please visit www.removab.com.

About the pivotal study

The study involved 258 patients with malignant ascites due to various carcinomas. Of those, 129 suffered from ovarian cancer, while another 129 had other types of cancer. Patients received paracentesis followed by four intraperitoneal infusions of Removab®, or paracentesis alone (control group). Details of the study results are published by Heiss et al, *Int J Cancer* 2010;127:2209–21

About Biomarker

A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, a pathogenic process, or pharmacologic responses to a therapeutic intervention.

About relative lymphocyte count (RLC)

The relative lymphocyte count describes the percentage of lymphocytes among the total of leukocytes in the peripheral blood.

About epithelial cell-adhesion molecule (EpCAM)

EpCAM is a tumor-associated antigen expressed on the vast majority of epithelial tumors. EpCAM is expressed on tumor cells in the ascites fluid of patients with EpCAM-positive tumors.

About malignant ascites

Malignant ascites can be caused by various kinds of tumors. The peritoneal spread of tumor cells leads to an accumulation of fluid in the peritoneal cavity and is associated with an unfavorable prognosis for the patient. The most common method of treatment is paracentesis, which generally must be repeated at intervals of one to two weeks and can lead to complications such as infections or elevated losses of fluids and proteins. Removab® destroys the peritoneal cancer cells and thus directly attacks the cause of malignant ascites.

About EORTC QLQ-C30

The EORTC QLQ-C30 is a quality of life questionnaire designed for use in a wide range of cancer patients. It is an accepted and valid measure of QoL in cancer patients. The EORTC QLQ-C30 has been translated into and validated in more than 80 different languages.

###

Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2010, Group sales were approximately €16.0 billion. On March 31, 2011, the Fresenius Group had 140,111 employees worldwide. For more information, visit the company's website at www.fresenius.com.

Fresenius Biotech, 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 headquartered in Munich. For more information, please visit www.fresenius-biotech.com.

Removab® is a registered trademark of Fresenius Biotech.

Fresenius SE & Co. KGaA
Registered Office: Bad Homburg, Germany
Commercial Register: Amtsgericht Bad Homburg, HRB 11852
Chairman of the Supervisory Board: Dr. Gerd Krick

General Partner: Fresenius Management SE
Registered Office: Bad Homburg, Germany
Commercial Register: Amtsgericht Bad Homburg, HRB 11673
Management Board: Dr. Ulf M. Schneider (Chairman), Rainer Baule, Dr. Francesco De Meo, Dr. Jürgen Götz, Dr. Ben Lipps, Stephan Sturm, Dr. Ernst Wastler
Chairman of the Supervisory Board: Dr. Gerd Krick