

# Swedish Orphan Biovitrum agrees with Fresenius Biotech to distribute Removab®

Stockholm, Sweden - January 27, 2011 - Swedish Orphan Biovitrum (STO: SOBI) today announced a Removab distribution agreement with Fresenius Biotech. Under the agreement Swedish Orphan Biovitrum (Sobi) will distribute Removab exclusively in 15 European countries over 7 years.

Removab was granted marketing authorization by the European Commission in April 2009 for the treatment of malignant ascites associated with cancer and has been launched in Germany and Austria so far. The territories in which Sobi will distribute Removab are Sweden, Denmark, Norway, Finland, Iceland, Poland, Czech Republic, Slovakia, Slovenia, Romania, Bulgaria, Hungary, Estonia, Latvia and Lithuania.

"Removab" is an innovative product that holds great value to patients with high medical needs. We are looking forward to the Fresenius Biotech partnership and the additional growth potential Removab will add to our business. Moreover, Removab is a perfect fit with our cancer product portfolio such as Yondelis which is distributed in similar territories," said Kennet Rooth, CEO of Sobi.

"The agreement with SOBI is part of our strategy of complementing our own marketing and sales activities with strong partnerships in additional territories. We appreciate that more patients are now able to benefit from Removab®," said Christian Schetter, CEO of Fresenius Biotech.

# **About Removab** (catumaxomab)

Removab® is a registered trade mark by Fresenius Biotech GmbH. It is the first drug worldwide with a regulatory label for the treatment of malignant ascites. Removab® is a tri-functional antibody licensed from TRION Pharma GmbH. The therapeutic objective of Removab® is to generate a strong immune reaction against cancer cells resulting in their elimination.

The EU approval is based on the results of a large international phase II/III pivotal study which demonstrated a statistically significant four-fold increase in puncture-free survival over a therapy with puncture alone. Removab® effectively destroys cancer cells in the peritoneal cavity and therefore attacks the primary cause of ascites formation. This leads to a prolongation to the time to next paracentesis, a reduction of the number of painful and burdensome punctures and an improvement of the patients' quality of life and daily function. In addition, the results of the study indicate a positive impact on overall survival.

Removab® is approved for the treatment of malignant ascites in patients with EpCAM (Epithelial Cell Adhesion Molecule) positive carcinomas where standard therapy is not available or no longer feasible.

EpCAM is a tumor-associated antigen expressed on the vast majority of carcinomas (epithelial tumors). Furthermore, the vast majority of carcinoma-induced malignant ascites contain EpCAM positive tumor cells. In healthy tissue, EpCAM is not accessible to binding, which makes it an attractive antigen for tumor specific targeting.

### **About malignant ascites**

Malignant ascites is the accumulation of fluid in the abdominal cavity mainly due to abdominal spread of cancer cells and it is associated with a poor prognosis. Malignant ascites can be caused by different carcinomas. It is most common in ovarian, pancreatic and gastric cancers with an incidence of 20 to 50% of all cases. Malignant ascites develops late in the course of the cancer disease and regularly has a strong impact on the patient's quality of life. The most commonly used treatment of malignant ascites is puncture (paracentesis), which has to be carried out repeatedly and can lead to complications such as infection and fluid or protein deprivation.

#### **About Fresenius and Fresenius Biotech**

Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2009, Group sales were approximately €14.2 billion. On Sept. 30, 2010, the Fresenius Group had 136,458 employees worldwide. For more information visit the Company's website at <a href="https://www.fresenius.com">www.fresenius.com</a>.

**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 with headquarters in Munich. For more information please visit <a href="www.fresenius-biotech.com">www.fresenius-biotech.com</a>.

# **About Swedish Orphan Biovitrum (Sobi)**

Sobi is a Swedish based niche specialty pharmaceutical company with an international market presence. The company is focused on providing and developing specialist pharmaceuticals for rare disease patients with high medical needs. The portfolio consists of about 60 marketed products and an emerging late stage clinical development pipe-line. Our focus areas are: hemophilia, inflammation/autoimmune diseases, fat malabsorption, cancer and inherited metabolic disorders. Sobi had pro-forma revenues 2009e of about 2 BSEK and approximately 500 employees. The head office is located in Sweden and the share (STO: SOBI) is listed on NASDAQ OMX Stockholm. For more information please visit <a href="https://www.sobi.com">www.sobi.com</a>.

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Swedish Orphan Biovitrum may be required to disclose the information provided herein pursuant to the Swedish Securities Markets Act. The information was provided for public release on January 27, 2011 at 8:30 a.m. CET.