Swedish Orphan Biovitrum's Long-Lasting Hemophilia A Therapy Receives Orphan Drug Designation in the US

Stockholm, Sweden – Dec 23, 2010 - Swedish Orphan Biovitrum (STO: SOBI) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to its long-lasting, fully-recombinant Factor VIII Fc fusion protein (rFVIIIFc) for the treatment of hemophilia A. rFVIIIFc is being developed in partnership **with Biogen Idec (NASDAQ: BIIB).**

A global registrational trial of rFVIIIFc (A-LONG) is ongoing. The phase II/III trial is an open-label, multicenter clinical trial designed to evaluate the safety, pharmacokinetics and efficacy of rFVIIIFc in the prevention and treatment of bleeding in previously-treated patients with severe hemophilia A.

"The orphan drug designation (ODD) for rFVIIIFc is an important step in our efforts to bring an important new, valuable and needed treatment to hemophilia A patients. An ODD gives advantages in FDA assistance, user-fee benefits and, after orphan drug registration, seven years of market exclusivity," said Peter Edman, Ph.D., Chief Scientific Officer of Swedish Orphan Biovitrum (Sobi).

About rFVIIIFc and the recombinant Fc-Fusion protein hemophilia program

Treatment of severe hemophilia A requires frequent infusions, creating a significant burden for individuals with the condition. The rFVIIIFc molecule is being investigated for the potential to prolong protection from bleeding and reduce the frequency of injections for both prophylaxis and on-demand therapy in hemophilia A.

rFVIIIFc is a recombinant Factor VIII Fc fusion protein developed using monomeric Fc fusion technology. The technology makes use of a natural mechanism that recycles rFVIIIFc in the circulation to extend its half-life. It is a fully-recombinant clotting factor designed to replace the protein that hemophilia A patients lack and to last longer in the body than commercially-available Factor VIII products.

The registrational trial of rFVIIIFc is expected to enroll approximately 150 patients in 60 centers globally. The A-LONG study will include male patients aged 12 years and above who have a diagnosis of severe hemophilia A, a history of at least 150 documented prior exposure days to any currently-marketed Factor VIII product and a platelet count of ≥100,000 cells/µL. Patients will be assigned into three arms: high-dose prophylaxis, low-dose prophylaxis and on-demand.

The decision to progress rFVIIIFc into a registrational trial was based on strong Phase I/IIa clinical data and supportive preclinical data. In July, Biogen Idec and Swedish Orphan Biovitrum announced data from the Phase I/IIa open-label, dose-escalation study that evaluated the safety and pharmacokinetics of an intravenous injection of rFVIIIFc in16 previously-treated patients with severe hemophilia A. In the study, rFVIIIFc demonstrated a prolonged half-life compared to Advate® and was well tolerated with no drug

related serious adverse events. Adverse events were observed in 11 out of 16 patients, with only one related to study drug – dysguesia (abnormal taste in the mouth).

Using the same technology as rFVIIIFc, Biogen Idec and Sobi are also developing a fully-recombinant, long-lasting Factor IX Fc fusion protein (rFIXFc) for the treatment of hemophilia B. rFIXFc is currently being evaluated in a registrational, open-label, multicenter trial (B-LONG) designed to evaluate its safety, pharmacokinetics and efficacy in hemophilia B patients. For more information on the rFIXFc and rFVIIIFc trials, please visit www.biogenidechemophilia.com or www.clinicaltrials.gov.

About Hemophilia A

Hemophilia A is a rare, inherited disorder in which the ability of a person's blood to clot is impaired. Hemophilia A occurs in about one in 5,000 male births annually and is caused by having substantially reduced or no Factor VIII protein, which is needed for normal blood clotting. People with hemophilia A therefore need injections of Factor VIII to restore the coagulation process and prevent frequent bleeds that could otherwise lead to pain, irreversible joint damage and life-threatening hemorrhages. Prophylaxis treatment with infusions three times per week or every other day to maintain a sufficient circulating level of coagulation factor is being increasingly used, and long-term studies demonstrate that such regimens increase the patient's life expectancy and greatly reduce, if not eliminate, progressive joint deterioration.

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 www.sobi.com.

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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 December 23, 2010, 8.30 am CET.