Biogen Idec and Swedish Orphan Biovitrum Announce First Patient Dosed in Global Registrational Trial of Long-Lasting Recombinant Factor VIII Fc Fusion Protein

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First Long-Lasting Factor VIII Candidate in Late-Stage Clinical Trial for Treatment of Hemophilia A

WESTON, Mass. & STOCKHOLM--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Swedish Orphan Biovitrum (STO: SOBI) today announced that the first patient has been dosed with the companies' long-lasting recombinant Factor VIII Fc fusion protein (rFVIIIFc) in a global registrational clinical trial. The study, called A-LONG, is an open-label, multicenter, Phase 2/3 study designed to evaluate the safety, pharmacokinetics and efficacy of rFVIIIFc in previously-treated hemophilia A patients.

"Treatment of hemophilia A involves frequent injections that can often be a major burden for individuals with the disorder, as well as their families," said John Pasi, M.D., Co-Principal Investigator of the A-LONG trial and Professor of Haemostasis and Thrombosis, Barts and The London School of Medicine and Dentistry, London. "There is a significant unmet need for a Factor VIII product, like rFVIIIFc, with the potential to prolong protection from bleeding and yet reduce the frequency of infusions, as well as potentially reduce the complications of hemophilia and improve the quality of life for these patients."

rFVIIIFc is a fully-recombinant clotting factor developed using Biogen Idec's novel and proprietary monomeric Fc fusion technology. The A-LONG trial is designed to evaluate different dosing regimens of rFVIIIFc in the prevention of bleeding as measured by the number of breakthrough bleeding episodes over the study period. The study will also evaluate the efficacy of rFVIIIFc in on-demand and surgical settings, and compare the pharmacokinetics of a single dose of rFVIIIFc with a single dose of a commercially-available recombinant Factor VIII product (Advate,® antihemophilic factor recombinant, plasma/albumin-free method, rFVIII).

"Dosing the first patient in the A-LONG study is an important milestone in our progress toward developing a treatment that has the potential to make a difference for the hemophilia A community," said Glenn Pierce, M.D., Ph.D., Vice President and Chief Medical Officer of Biogen Idec's hemophilia therapeutic area. "This trial, along with the ongoing Phase 2/3 study of our fully-recombinant, long-lasting Factor IX Fc fusion protein for the treatment of hemophilia B, further demonstrates our strong commitment to developing better treatments for the worldwide hemophilia community."

"rFVIIIFc is an innovative therapy that offers the potential to make a positive impact in the lives of people with hemophilia A," said Peter Edman, Ph.D., Chief Scientific Officer of Swedish Orphan Biovitrum. "The initiation of this trial builds on the positive data that we saw in our Phase 1/2a study, and it is also an exciting achievement for Swedish Orphan Biovitrum."

About The A-LONG Study

A-LONG 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 trial is expected to enroll approximately 150 patients in 60 centers globally. The 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 study's objectives are to evaluate the safety and tolerability of rFVIIIFc, which will be measured by evaluating clinically notable changes from baseline in physical examinations, vital signs, lab values, and incidence of adverse events and inhibitor development. The study will also assess the potential of rFVIIIFc to enable protection from bleeding by evaluating the number of both spontaneous and traumatic bleeding episodes in each treatment arm. The A-LONG trial will evaluate different dosing regimens of rFVIIIFc in the prevention of bleeding. Secondary endpoints include total rFVIIIFc consumption per subject, response to treatment and the pharmacokinetics of a single dose of rFVIIIFc versus Advate.

About rFVIIIFc And The Recombinant Fc-Fusion Protein Hemophilia Program

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 decision to progress rFVIIIFc into a registrational trial was based on strong Phase 1/2a clinical data and supportive preclinical data. In July, Biogen Idec and Swedish Orphan Biovitrum announced data from the Phase 1/2a open-label, dose-escalation study that evaluated the safety and pharmacokinetics of an intravenous injection of rFVIIIFc in 16 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 proprietary monomeric Fc fusion technology as rFVIIIFc, Biogen Idec and Swedish Orphan Biovitrum 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 Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market biological products for the treatment of serious diseases with a focus on neurological disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than $4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About Swedish Orphan Biovitrum

Swedish Orphan Biovitrum 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 pipeline. Our focus areas are: hemophilia, inflammation/autoimmune diseases, fat malabsorption, cancer and inherited metabolic disorders.

Swedish Orphan Biovitrum 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.

Safe Harbor

This press release contains forward-looking statements regarding the development of long-lasting hemophilia therapies, which may be identified by words such as "believe," "expect," "may," "plan," "will" and similar expressions. These statements are based on the companies' current beliefs and expectation. Drug development involves a high degree of risk. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that we may not fully enroll our planned clinical trials, unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information, further studies, or may fail to approve the drug, or the companies may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with Biogen Idec's drug development and other activities, see the periodic reports of Biogen Idec filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and the companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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 Dec 6, 2010 at 8:30 a.m. CET.

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