Biogen Idec and Sobi Initiate Global Clinical Trials of Long-Lasting Hemophilia A and B Product Candidates in Children

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WESTON, Mass. & STOCKHOLM--(BUSINESS WIRE)--Biogen Idec (NASDAQ:BIIB) and Swedish Orphan Biovitrum (STO:SOBI) today announced the initiation of two global pediatric clinical trials of the companies' long-lasting recombinant Factor VIII and Factor IX Fc fusion proteins (rFVIIIFc and rFIXFc) in hemophilia A and B.

rFVIIIFc and rFIXFc are fully-recombinant clotting factors developed using Biogen Idec's novel and proprietary monomeric Fc-fusion technology, which makes use of a natural mechanism to recycle rFVIIIFc and rFIXFc in the circulation in the body. Biogen Idec and Sobi are studying this technology to see whether it extends half-life and enables the proteins to last longer in the body than commercially-available factor products.

"Children with hemophilia share a need for long-lasting factor products that may prolong protection from bleeding and reduce the frequency of intravenous infusions," said Glenn Pierce, M.D., Ph.D., senior vice president of Global Medical Affairs and chief medical officer of Biogen Idec's hemophilia therapeutic area. "The pediatric clinical trials are an important complement to the ongoing adult studies and further demonstrate our commitment to develop new treatments for the hemophilia community."

"With these studies, we extend the clinical development of rFVIIIFc and rFIXFc to address a broader patient population including children with hemophilia," said An van Es-Johansson, M.D., head of clinical development at Sobi. "The initiation of these studies represents an important milestone for our clinical development program and supports our global registration strategy for the products."

The clinical trials are open-label, multicenter studies designed to evaluate the safety, pharmacokinetics and efficacy of rFVIIIFc and rFIXFc in previously-treated children with severe hemophilia A or B under the age of 12 years. The first patient has been dosed in the rFIXFc pediatric study, and the rFVIIIFc pediatric study is now actively recruiting patients. Global registration studies of rFVIIIFc and rFIXFc are ongoing in previously-treated patients with severe hemophilia A or B aged 12 years and over, with data readouts expected in the second half of the year.

About the Kids A-LONG study

The Kids A-LONG study is an open-label, multicenter study designed to evaluate the safety, pharmacokinetics and efficacy of rFVIIIFc in the prevention and treatment of bleeding episodes in previously-treated pediatric patients with hemophilia A. The study will include approximately 50 male patients under the age of 12 who have a diagnosis of severe hemophilia A and a history of at least 50 documented prior exposure days with any currently-marketed Factor VIII product. All patients will be treated with a twice weekly prophylactic dosing regimen.

The primary outcome measure is the frequency of inhibitor development over an approximately 26-week treatment period and at least 50 exposure days to rFVIIIFc. Secondary outcome measures include the number of annualized bleeding episodes and assessments of response to treatment over the same time period. For more information on the study, visit www.biogenidechemophilia.com or www.clinicaltrials.gov (NCT01458106).

About the Kids B-LONG study

The Kids B-LONG study is an open-label, multicenter study designed to evaluate the safety, pharmacokinetics and efficacy of rFIXFc in the prevention and treatment of bleeding episodes in previously-treated pediatric patients with hemophilia B. The study will include approximately 26 male patients under the age of 12 who have a diagnosis of severe hemophilia B and a history of at least 50 documented prior exposure days with any currently-marketed Factor IX product. All patients will be treated with a weekly prophylactic dosing regimen.

The primary outcome measure is the frequency of inhibitor development over an approximately 50-week treatment period and at least 50 exposure days to rFIXFc. Secondary outcome measures include the number of annualized bleeding episodes and assessments of response to treatment over the same time period. For more information on the study, visit www.biogenidechemophilia.com or www.clinicaltrials.gov (NCT01440946).

About Hemophilia

Hemophilia is a rare, inherited disorder in which the ability of a person's blood to clot is impaired. Hemophilia A occurs in about 1 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. Hemophilia B occurs in about 1 in 25,000 male births annually and is caused by having substantially reduced or no Factor IX protein. People with hemophilia A and B therefore need injections of Factor VIII and Factor IX, respectively, to restore the coagulation process and prevent frequent bleeds that could otherwise lead to pain, irreversible joint damage and life-threatening hemorrhages. Prophylaxis treatment for hemophilia A and B requires infusions three to four times a week or two times a week, respectively, to maintain a sufficient circulating level of coagulation factor. 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

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune 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 $5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About Swedish Orphan Biovitrum (Sobi)

Sobi is a leading integrated biopharmaceutical company dedicated to bringing innovative therapies and services to improve the health of rare disease patients and their families. The product portfolio comprises about 45 marketed products as well as projects in the late clinical phase. Key therapeutic areas are Inflammation and Genetics & Metabolism. In 2011 Sobi had revenues of SEK 1.9 billion and around 500 employees. The share (STO: SOBI) is listed on OMX NASDAQ Stockholm. More information is available at www.sobi.com.

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