PRESS RELEASE

Stockholm, 21 March 2014

Health Canada approves Alprolix™

Swedish Orphan Biovitrum AB's (pupl) (Sobi) partner Biogen Idec today announced that Health Canada has approved Alprolix™ (Coagulation Factor IX (Recombinant), Fc fusion protein), rFIXFc, for the control and prevention of bleeding episodes and routine prophylaxis in adults, and children aged 12 and older, with haemophilia B. Alprolix is the first approved long-acting haemophilia B therapy and is indicated to prevent or reduce the frequency of bleeding episodes with prophylactic injections scheduled once weekly or once every 10-14 days.

This is the first regulatory approval worldwide for Alprolix, which is currently under review by regulatory authorities in several other countries, including the United States, Australia and Japan.

"This first approval of this long-acting therapy for people with haemophilia B is an important milestone in our joint collaboration with Biogen Idec and marks the first significant advance in the treatment for this group in almost 20 years," said Geoffrey McDonough, President and CEO of Sobi. "We are proud to be part of this therapeutic advancement and look forward to bringing this treatment to people with haemophila."

The Health Canada approval of Alprolix is based on results from the global, phase 3 B-LONG study. It demonstrated that Alprolix safely and effectively prevented, or reduced, bleeding episodes with prophylactic injections given once weekly or once every 10-14 days in adults and adolescents with severe haemophilia B. In addition, more than 90 percent of all bleeding episodes were controlled by a single Alprolix injection.

Prior to EU filing it is necessary to complete studies in paediatrics under the age of 12. Currently there is an ongoing phase 3 study in children with haemophilia B under the age of 12 called Kids B-LONG. Pending the outcome of the paediatric study, Sobi plans to file for market authorisation of the product in Sobi's territories, i.e. Europe, Russia, North Africa and the Middle East.

About Haemophilia B

Haemophilia B is a rare, inherited disorder in which the ability of a person's blood to clot is impaired. Haemophilia B occurs in about one in 25,000 male births annually, and more rarely in females. The World Federation of Haemophilia global survey conducted in 2011 estimates that more than 25,000 people are currently diagnosed with haemophilia B worldwide. It is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting. People with haemophilia B experience prolonged bleeding episodes that can cause pain, irreversible joint damage and life-threatening haemorrhages. Prophylactic injections of factor IX can temporarily replace the missing clotting factors that are needed to control bleeding and prevent new bleeding episodes. The Medical and Scientific Advisory Council of the National Hemophilia Foundation recommends prophylaxis as the optimal therapy for people with severe haemophilia B.

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About the B-LONG Study
B-LONG was a global, open-label, multi-center phase 3 study that evaluated the efficacy, safety and pharmacokinetics (measurement of the presence of the therapy in a patient's body over time), of Alprolix in 123 males aged 12 years and older with haemophilia B. These findings were published in the December 12, 2013 issue of The New England Journal of Medicine. The study involved 50 haemophilia treatment centres in 17 countries on six continents.

The overall median annualized bleeding rates (ABR), or projected rate of bleeding episodes per year, reported in the study were 2.95 for the weekly prophylaxis arm (arm 1) and 1.38 for individualised-interval prophylactic regimens (arm 2), in which the dosing interval started at every 10 days, and 17.69 in the on-demand treatment arm (arm 3). The overall median dosing interval with individualised-interval prophylaxis was 12.5 days. During the last six months of the study, the median dosing interval was 13.8 days.

The most common adverse events (incidence of ≥5 percent in a pooled analysis of arms 1, 2, and 3) were nasopharyngitis (common cold), influenza (flu), arthralgia (joint pain), upper respiratory tract infection, hypertension (high blood pressure) and headache.

About Alprolix
Alprolix [Coagulation Factor IX (Recombinant), Fc fusion protein] is the first long-acting fully recombinant clotting factor therapy. It is indicated for the control and prevention of bleeding episodes and routine prophylaxis in adults, and children 12 years and older, with haemophilia B. Alprolix is developed by fusing factor IX to the Fc portion of Immunoglobulin G Subclass [1], or IgG1 (protein commonly found in the body). It is believed that this enables Alprolix to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion has been used for more than 15 years, Biogen Idec is the only company to apply it in haemophilia.

About the Biogen Idec and Sobi Collaboration
Biogen Idec and Swedish Orphan Biovitrum (Sobi) are partners in the development and commercialisation of Alprolix for haemophilia B. Biogen Idec leads development, has manufacturing rights, and has commercialisation rights in North America and all other regions in the world excluding the Sobi territory. Sobi has the right to opt in to assume final development and commercialisation in Europe, (including Russia), the Middle East and Northern Africa.

About Sobi
Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Inflammation and Genetic diseases, with three late stage biological development projects within Haemophilia and Neonatology. We also market a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2013, Sobi had total revenues of SEK 2.2 billion (€253 M) and about 550 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

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