

PRESS RELEASE

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US FDA approves Alprolix™

Swedish Orphan Biovitrum AB's (publ) (Sobi) partner Biogen Idec have announced that the US Food and Drug Administration (FDA) has approved Alprolix (Coagulation Factor IX (Recombinant), Fc fusion protein), the first recombinant, DNA derived haemophilia B therapy with prolonged circulation in the body. Alprolix is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with haemophilia B. The therapy is shown to reduce bleeding episodes with prophylactic (protective) infusions starting at least a week apart.

"The FDA approval for Alprolix will offer people with haemophilia B a new treatment option which can help reduce the burden of prophylactic injections," said Geoffrey McDonough, President and CEO of Sobi. "We are proud to be part of this therapeutic advance through our collaboration with Biogen Idec."

Alprolix was recently approved by Health Canada for the treatment of haemophilia B and is currently under review by regulatory authorities in several other countries including Australia and Japan.

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 approximately one in 25,000 male births annually, and more rarely in females. The World Federation of Haemophilia global survey conducted in 2012 estimates that more than 28,000 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.

About the B-LONG Study

B-LONG was a global, open-label, multi-centre phase 3 study that evaluated the efficacy, safety and pharmacokinetics, of Alprolix in 123 males aged 12 years and older with haemophilia B. The study involved 50 haemophilia treatment centres in 17 countries on six continents.

The overall median annualised bleeding rates (ABR), or projected rate of bleeding episodes per year, reported in the study were 3.0 for weekly the prophylaxis arm, 1.4 for the individualised- interval prophylaxis arm and 17.7 in the on-demand treatment arm. For 12 study participants undergoing 14 major surgical procedures, treating physicians rated the ability of Alprolix to control bleeding as “excellent” or “good” in 100 per cent of these surgeries.

Common adverse reactions (incidence of greater than or equal to 1 per cent) from the B-LONG study were headache and oral paresthesia (an abnormal sensation in the mouth).

About Alprolix

Alprolix™ [Coagulation Factor IX (Recombinant), Fc Fusion Protein] is the first recombinant, clotting factor therapy with prolonged circulation in the body. It is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with haemophilia B. Alprolix is not indicated for immune tolerance induction therapy, which is a treatment for people with inhibitors, and should not be used in individuals with a known history of serious allergic reactions. 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 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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