PRESS RELEASE

Stockholm, Sweden 25 October 2017

Alprolix® approved in the Kingdom of Saudi Arabia for the treatment of haemophilia B

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the Saudi Food & Drug Authority (SFDA) in the Kingdom of Saudi Arabia has approved Alprolix® (eftrenonacog alfa), for the treatment of haemophilia B. Alprolix is the first extended half-life and recombinant factor IX Fc fusion protein therapy approved for the treatment of haemophilia B in Saudi Arabia.

"We are very pleased Alprolix is now approved in Saudi Arabia, which will enable physicians to offer their patients with haemophilia B a wider range of treatment options and the opportunity to experience extended protection from bleeds", says Ahmad Abu-Dahab, Regional Director Middle East & Turkey. "We will now focus on ensuring timely and sustainable access to treatment across the country".

Alprolix is indicated for treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency) and it can be used for all age groups.

The Saudi Arabia approval was based on data from the phase 3 clinical studies B-LONG, which demonstrated the efficacy, safety and pharmacokinetics of eftrenonacog alfa in previously treated males 12 years of age and older with severe haemophilia B, and Kids B-LONG which demonstrated the efficacy and safety of eftrenonacog alfa in previously treated male children with haemophilia B under 12 years of age.

About Alprolix®

Alprolix® (eftrenonacog alfa, Coagulation Factor IX (Recombinant), Fc Fusion Protein), is a recombinant clotting factor therapy developed for haemophilia B using Fc fusion technology to prolong circulation in the body. It is engineered by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling Alprolix to use a naturally occurring pathway to extend the time the therapy remains in the body (half-life). While Fc fusion technology has been used for more than 15 years, Bioverativ and Sobi have optimized the technology and are the first companies to utilize it in the treatment of haemophilia. Alprolix is manufactured using a human cell line in an environment free of animal and human additives.

Alprolix is approved and marketed by Sobi for the treatment of haemophilia B in the EU, Iceland, Liechtenstein, Kuwait, Norway and Switzerland, as well as in the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries where Bioverativ has the marketing rights.

Allergic-type hypersensitivity reactions and development of inhibitors have been observed with Alprolix in the treatment of haemophilia B, including in previously untreated patients. Note that the indication for previously untreated patients is not included in the Saudi Arabian Product Information.

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About haemophilia B
Haemophilia B is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting.[i] The World Federation of Hemophilia estimates that approximately 28,000 people are currently diagnosed with haemophilia B worldwide.[ii]

People with haemophilia B may experience bleeding episodes in joints and muscles that cause pain, decreased mobility and irreversible joint damage. In the worst cases, these bleeding episodes can cause organ bleeds and life-threatening haemorrhages. Injections of factor IX temporarily replace clotting factors necessary to resolve bleeding and, when used prophylactically, to prevent new bleeding episodes.[i]

About the Sobi and Bioverativ collaboration
Sobi and Bioverativ collaborate on the development and commercialisation of Alprolix and Elocta/ELOCTATE. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Bioverativ has final development and commercialisation rights in North America and all other regions in the world excluding the Sobi territory, and has manufacturing responsibility for Elocta/ELOCTATE and Alprolix.

About Sobi™
Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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[i] World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: http://www.wfh.org/en/page.aspx?pid=637#Difference_A_B. Accessed on: January, 13, 2017.
[ii] World Federation of Hemophilia. Report on the Annual Global Survey 2013. Available at: http://www1.wfh.org/publications/files/pdf-1591.pdf. Accessed on: January 13, 2017.