PRESS RELEASE

Stockholm, Sweden 27 June 2017

EMA approves the potential to dose every 14 days or longer in updated dosing regimen for Alprolix®

Swedish Orphan Biovitrum AB (publ) (Sobi™) has received approval from the European Medicines Agency (EMA) to update the dosing information for Alprolix® (eftrenonacog alfa). 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 dosing information in the product information now includes that patients on long-term prophylaxis to protect against bleeding and who are well controlled on a 100 IU/kg once every 10 days regimen, might be treated on an interval of 14 days or longer.

"We are very pleased with the approval of the updated dosing regimen for Alprolix that offers the potential to extend the dosing regimen to 14 days or longer based on patient's response. We are committed to improving the lives of people with Haemophilia B, and consider this an important step forward to reduce the treatment burden", says Milan Zdravkovic, Senior Vice President, Chief Medical Officer and Head of Research & Development at Sobi.

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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 Bioverativ for the treatment of haemophilia B in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, and Bioverativ has marketing rights in these regions. It is also authorised in the European Union, Iceland, Liechtenstein, Norway and Switzerland, where it is marketed by Sobi.

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 EU Product Information.

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 Bioverativ and Sobi™ collaboration
Bioverativ and Sobi collaborate on the development and commercialisation of Alprolix and ELOCTATE/Elocta. 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 ELOCTATE and Alprolix. Sobi has final development and commercialization rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets).

Bioverativ was created as a spin-off from Biogen's hemophilia business and separated from Biogen effective February 1, 2017. Bioverativ is an independent, publicly-traded company, headquartered in Waltham, Massachusetts, USA. During a temporary, transition period, which includes time to allow Bioverativ to establish certain licenses and consents related to ELOCTATE® and ALPROLIX, each of Bioverativ and Biogen will have a relationship to the products.

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.