PRESS RELEASE

Stockholm, 3 October 2016

European Commission approves transfer of marketing authorisation for Alprolix® to Sobi™

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the European Commission (EC) has approved the transfer of the marketing authorisation for Alprolix® (eftrenonacog alfa), a recombinant clotting factor therapy developed for the treatment of haemophilia B, from Biogen[i] to Sobi, making Sobi the marketing authorisation holder (MAH) in the EU. The EC has also approved the transfer of the orphan designation to Sobi.

As MAH, Sobi will assume full regulatory responsibility for Alprolix in the EU.

The EC approval of Alprolix on 12 May 2016 was based on results from two global phase 3 clinical trials that demonstrated the efficacy, safety and pharmacokinetics of Alprolix for the treatment of haemophilia B: the pivotal B-LONG study for previously treated adults and adolescents, and the Kids B-LONG study for previously treated children under age 12.

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About haemophilia B

Haemophilia is a rare, genetic 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. Worldwide, it is estimated that between 60, 000 and 80,000[ii] people are living with haemophilia B.

People with haemophilia B experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening haemorrhages. Prophylactic infusions of factor IX can temporarily replace the clotting factor needed to control bleeding and prevent new bleeding episodes.[iii] The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.[iv]

About Alprolix®

Alprolix® (eftrenonacog alfa) is a recombinant clotting factor therapy developed for haemophilia B by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables Alprolix to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Sobi and Biogen are the first companies to utilise it in the treatment of haemophilia.

Alprolix is currently approved for the treatment of haemophilia B in the European Union, Iceland, Liechtenstein and Norway, as well as the United States, Canada, Japan, Australia, New Zealand and other countries. As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur following administration of Alprolix.

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About the Sobi and Biogen collaboration

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

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 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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[i] Biogen Idec Ltd
[ii] Srivastava et al. Haemophilia (2013), 19, e1–e47
[iii] 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: June 17, 2016.
[iv] Guideline for the management of hemophilia, World Federation of Hemophilia, 2nd edition, http://www1.wfh.org/publication/files/pdf-1472.pdf. Accessed on December 2015