PRESS RELEASE

Stockholm, Sweden, 21 November 2016

Elocta® approved in Kuwait for the treatment of haemophilia A

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the Ministry of Health in Kuwait has approved Elocta® (efmoroctocog alfa), a recombinant human factor VIII Fc-fusion protein with an extended half-life, for the treatment of haemophilia A. Elocta is the first recombinant factor VIII Fc fusion protein therapy approved for the treatment of haemophilia A in the Middle East region.

"The approval of Elocta in Kuwait is an important development for the haemophilia community in the Middle East and brings physicians, and their patients a wider range of treatment options" said Ahmad Abu-Dahab, Regional Director Middle East, & Turkey. "We will now focus on ensuring timely and sustainable access to Elocta for people living with haemophilia A across other Middle Eastern states."

Elocta is indicated for both on-demand and prophylaxis treatment of people with haemophilia A of all ages.

The Kuwait approval was based on data from Elocta's pivotal, phase 3 A-LONG clinical study, which demonstrated the efficacy, safety and pharmacokinetics of efmoroctocog alfa in previously treated males 12 years of age and older with severe haemophilia A, and from the phase 3 Kids A-LONG clinical study, which demonstrated the efficacy and safety of efmoroctocog alfa in previously treated male children with haemophilia A under 12 years of age.

About Haemophilia A

Haemophilia is a rare, genetic disorder in which the ability of a person's blood to clot is impaired. Haemophilia A occurs in about one in 5,000 male births annually, and more rarely in females.

People with haemophilia A experience prolonged bleeding episodes that can cause pain, irreversible joint damage and life-threatening haemorrhages. Prophylactic infusions of factor VIII can temporarily replace the missing clotting factors that are needed to control bleeding and prevent new bleeding episodes.[i] The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.[ii]

About Elocta®/Eloctate®

Elocta (efmoroctocog alfa), the first recombinant clotting factor VIII therapy that offers an extended half-life in the body, is approved in the European Union, Switzerland, Iceland, Liechtenstein and Norway, as well as the United States, Canada, Australia, New Zealand, Brazil, Taiwan and Japan (as Eloctate). It was developed for haemophilia A by fusing factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables Elocta 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.

As with any factor replacement therapy, development of inhibitors may occur following administration of Elocta/Eloctate.

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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] 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.
[ii] Guideline for the management of hemophilia, World Federation of Hemophilia, 2nd edition, http://www1.wfh.org/publication/files/pdf-1472.pdf. Accessed December 2015