PRESS RELEASE

Stockholm, 24 March 2016

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

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announced that the European Commission (EC) has approved the transfer of the marketing authorisation for Elocta® (efmoroctocog alfa) from Biogen[1] to Sobi, making Sobi the marketing authorisation holder (MAH) of Elocta in the EU.

Elocta is a recombinant human factor VIII Fc fusion protein with an extended half-life and is the first haemophilia A treatment in the EU to offer prolonged protection against bleeding episodes with prophylactic injections every three to five days. Elocta is indicated for treatment and prophylaxis of bleeding in patients with haemophilia A and can be used for all age groups.

As MAH Sobi will assume full legal responsibility for Elocta, from a regulatory perspective, during its entire life cycle.

The EC approval of Elocta on 19 November 2015 was based on data from the pivotal phase 3 A-LONG clinical study which demonstrated the efficacy, safety and pharmacokinetics of Elocta 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 Elocta in previously treated boys with haemophilia A under 12 years of age.

Sobi and Biogen are collaboration partners in the development and commercialisation of Elocta for haemophilia A. Sobi holds final development and commercialisation rights in a pre-specified territory, which includes Europe, North Africa, Russia and certain countries in the Middle East. Biogen leads development and manufacturing of the product and holds commercialisation rights in North America and all other regions in the world outside of the Sobi territory. Elocta is also approved in the U.S., Canada, Australia, New Zealand, Japan and other countries where it is known as Eloctate® (Antihemophilic Factor (Recombinant), Fc Fusion Protein).

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[1] Biogen Idec Ltd

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About Elocta®

Elocta® (efmoroctocog alfa) is the first recombinant clotting factor VIII therapy in the EU that offers an extended half-life in the body. It is indicated for the treatment and prophylaxis of bleeding episodes in patients with haemophilia A (factor VIII deficiency) and can be used by people of all ages. Elocta was developed by fusing B-domain deleted factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables Elocta to utilise a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used in other therapies for more than 15 years, Sobi and Biogen are the first companies to utilise it in the treatment of haemophilia. As with any infused protein, allergic type hypersensitivity reactions and development of inhibitors may occur following administration of Elocta. For full prescribing information visit www.elocta.com.

About Haemophilia A

Haemophilia A is a rare, chronic, genetic disorder in which the ability of a person's blood to clot is impaired due to missing or reduced levels of a protein known as factor VIII. People with haemophilia A experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening haemorrhages. According to the World Federation of Hemophilia, an estimated 140,000 people worldwide are identified as living with haemophilia A.[2]

Therapies for haemophilia A, the most common form of haemophilia, can be administered either on a schedule to help prevent or reduce bleeding episodes (prophylaxis) or to control bleeding when it occurs (on-demand). The World Federation of Hemophilia recommends that prophylaxis be the goal of therapy because it may prevent bleeding and joint destruction. As a result, regular prophylactic treatment may slow progression of joint disease and may improve quality of life.

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 primary focused on Haemophilia, Inflammation and Genetic diseases. We also market a portfolio of speciality and rare disease products for partner companies across Europe, the Middle East, North Africa and Russia. 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 approximately 700 employees. The share (STO:SOBI) is listed on NASDAQ Stockholm.

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[2] World Federation of Hemophilia. Annual Global Survey 2012. http://www1.wfh.org/publications/files/pdf-1574.pdf. Accessed July 2015