PRESS RELEASE

Stockholm, Sweden, 27 June 2016

Sobi's Elocta® (rFVIIIFc) approved in Switzerland for the treatment of haemophilia A

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO: SOBI) today announced that the Swiss Agency for Therapeutic Products, Swissmedic, has approved Elocta® (rFVIIIFc) for the treatment of haemophilia A. Elocta is the only recombinant factor VIII Fc fusion protein with an extended half-life approved for haemophilia A treatment in Switzerland to offer prolonged protection against bleeding episodes with prophylactic injections every three to five days.

"The Swiss approval of Elocta is an important milestone for the country's haemophilia A community, offering the potential to improve the care of people with haemophilia A," said Krassimir Mitchev, M.D., Ph.D., vice president and medical therapeutic area head of Haemophilia at Sobi. "Our focus is now to ensure timely and sustainable access to Elocta for people living with haemophilia A in Switzerland."

Elocta is indicated for both on-demand and prophylaxis treatment of people with haemophilia A of all ages. The Swiss approval was based on data from Elocta's pivotal, phase 3 A-LONG clinical study, which demonstrated the efficacy, safety and pharmacokinetics of rFVIIIFc 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 rFVIIIFc in previously treated male children with haemophilia A under 12 years of age.

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

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About Elocta®

Elocta® (efmoroctocog alfa) is the first recombinant clotting factor VIII therapy in Switzerland 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.swissmedicinfo.ch.

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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.[1]

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