PRESS RELEASE

Stockholm, 11 January 2016

Sobi™ announces commercial launch of Elocta® in first countries in Europe

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announced the commercial launch of Elocta® (efmoroctocog alfa) in first countries in Europe. 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 both prophylaxis and on-demand treatment of bleeding in people with haemophilia A and can be used for all age groups. The SmPC recommended prophylactic dose of Elocta is 50 IU/ kg every three to five days. The dose may be personalised by the treating physician in the range of 25 to 65 IU/kg depending on the severity of the factor VIII deficiency, the location and frequency of bleeding, and the patient's activity level and clinical condition.

“The launch of Elocta is an important milestone for the haemophilia community, offering people with haemophilia A in the EU a treatment option that provides extended protection against bleeds”, said Geoffrey McDonough, CEO and President at Sobi. “Since the approval of Elocta in the EU, our focus has been to ensure timely and sustainable access to Elocta for people living with haemophilia A. We are delighted to be able to announce that Elocta is now available.”

Elocta is a fully recombinant fusion protein produced from a human cell line without the addition of human- or animal-derived protein. The European Commission’s approval of Elocta 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 under 12 years of age with haemophilia A.

“Low annualised bleeding rates, comparable with those seen in the pivotal A-LONG and Kids A-LONG trials, have been observed during the ongoing open label, long term follow-up ASPIRE study, with most participants receiving prophylactic treatment with similar weekly Elocta consumption as in the pivotal phase 3 studies”, said Birgitte Volck, Senior Vice President, Chief Medical Officer at Sobi. “For long term prophylaxis Elocta offers a dosing regimen that can be personalised to meet the needs of each individual patient.”

Sobi and Biogen are collaboration partners in the development and commercialisation of Elocta for haemophilia A, which is also known as Eloctate® (Antihemophilic Factor (Recombinant), Fc Fusion Protein) in Australia, Canada, Japan, New Zealand and the U.S., where it is approved for the treatment of haemophilia A. Sobi holds final development and commercialisation rights in pre-specified territories, which include Europe,

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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.

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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.[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. 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 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 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

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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.