PRESS RELEASE

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First patients enrolled in 24 month real-world study evaluating effectiveness of Elocta®

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the first patients have been enrolled in the A-SURE study (NCT02976753). A-SURE is a 24-month real-world study evaluating the effectiveness of Elocta® compared to conventional FVIII products in the prophylactic treatment of patients with haemophilia A in Europe.

The efficacy and safety of Elocta have been established in clinical trials and the A-SURE study will provide data from a real-world setting, which can be made available to physicians, payers and reimbursement authorities in evaluating the effectiveness and usage of Elocta.

"Elocta is the first extended half-life FVIII product approved by the European Commission and, as such, represents a meaningful step in the treatment of haemophilia. Pharmacokinetic data from the phase 3 trials indicate that Elocta can achieve higher FVIII levels in plasma over a longer period of time as compared to the conventional haemophilia products given at the same dose. The clinical data shows that effective bleed prevention can be achieved with Elocta with extended dosing intervals. A-SURE is an important study that aims to evaluate the effectiveness of Elocta in a real world-setting. Sobi is committed to providing data to the haemophilia community on the potential opportunities Elocta can provide to the people living with haemophilia A," says Stefan Lethagen, Vice President Medical & Clinical Sciences, Haemophilia at Sobi.

The A-SURE study plans to enrol 350 patients in around 10 countries in Europe.

About A-SURE

The purpose of the A-SURE multicentre, non-interventional study is to evaluate the effectiveness of Elocta compared to conventional factor products in the prophylactic treatment of patients with haemophilia A over a 24-month prospective period. Data will also be collected for a 12-month retrospective period.

Study Population: Male patients with a diagnosis of haemophilia A prescribed prophylactic treatment with Elocta or conventional factor product. More information can be found at clinicaltrials.gov.

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. The World Federation of Hemophilia estimates that approximately 150 000 people are currently diagnosed with haemophilia A world-wide[i].

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

About Elocta®

Elocta® (efmoroctocog alfa) is a recombinant clotting factor VIII therapy developed for haemophilia A with prolonged circulation in the body using Fc fusion technology. It is engineered by fusing factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling Elocta to use a naturally occurring pathway to extend the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Sobi and Biogen have optimised the technology and are the first companies to utilise it in the treatment of haemophilia. Elocta is manufactured in a human cell line, using an environment free of animal and human additives.

Elocta is approved for the treatment of haemophilia A in the European Union, Switzerland, Iceland, Liechtenstein, Norway and Kuwait, marketed by Sobi; and, in the United States, Japan, Canada, Australia, New Zealand, Brazil and other countries is approved as Eloctate. Biogen has the marketing rights in these regions.

As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur in the treatment of haemophilia A. Inhibitor development has been observed with Elocta, including in previously untreated patients. Note that the indication for previously untreated patients is not included in the EU Product Information for Elocta.

About the Biogen and Sobi Collaboration
Biogen and Sobi collaborate on the development and commercialisation of Elocta/Eloctate and Alprolix. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Biogen has manufacturing responsibility for Eloctate/Elocta and Alprolix; and Biogen has final development and commercialisation rights for the products in North America and all other regions in the world excluding the Sobi territory. Biogen expects to spin off its haemophilia business into an independent, public company focused on haemophilia and other rare blood disorders on February 1, 2017. The planned spin-off, Bioverativ, will continue to collaborate with Sobi on their joint development programmes.

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, Annual Global Survey 2015, published in October 2016. Available at: http://www.wfh.org/en/data-collection
[ii] 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
[iii] 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