# PRESS RELEASE

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## Elocta® approved in the Kingdom of Saudi Arabia for the treatment of haemophilia A

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the Saudi Food & Drug Authority (SFDA) in the Kingdom of Saudi Arabia 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 extended half-life and recombinant factor VIII Fc fusion protein therapy approved for the treatment of haemophilia A in Saudi Arabia.

"The approval of Elocta in Saudi Arabia is an important development for the haemophilia community in the Middle East and will enable physicians to offer their patients a wider range of treatment options." says Ahmad Abu-Dahab, Regional Director Middle East, & Turkey.

"We will now focus on ensuring access to Elocta for people living with haemophilia A across other Middle Eastern states." says Ebrahim Al-Hagiri, Regulatory & Patient Access Manager Middle East & Turkey "This is a very important milestone to ensure that patients with haemophilia A have an early and sustainable access to this bleed prevention treatment."

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

The Saudi Arabia 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.

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**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 therapy developed for haemophilia A using Fc fusion technology to prolong circulation in the body. 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 Bioverativ have optimised the technology and are the first companies to utilise it in the treatment of haemophilia. Elocta is manufactured using a human cell line in an environment free of animal and human additives.

Elocta is approved and marketed by for the treatment of haemophilia A in the European Union, Switzerland, Iceland, Liechtenstein, Norway and Kuwait. It is approved and marketed as ELOCTATE® by Bioverativ in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, and Bioverativ has 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 Sobi™ and Bioverativ collaboration**
Sobi and Bioverativ collaborate on the development and commercialisation of Alprolix® and Elocta/ELOCTATE. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Bioverativ has final development and commercialisation rights in North America and all other regions in the world excluding the Sobi territory, and has manufacturing responsibility for Elocta and Alprolix.

Bioverativ was created as a spin-off from Biogen's hemophilia business and separated from Biogen effective February 1, 2017. Bioverativ is an independent, publicly-traded company, headquartered in Waltham, Massachusetts, USA. During a temporary, transition period, which includes time to allow Bioverativ to establish certain licenses and consents related to ELOCTATE and ALPROLIX, each of Bioverativ and Biogen will have a relationship to the products.

**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 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 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