PRESS RELEASE
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Elocta® obtains reimbursement in UK, Italy and France, complemented by real-world data and extensive patient experience

- *Patient access to Elocta is increasing, contributing to further evidence generation and real-world patient experience for extended half-life factor VIII therapy*

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the company's product Elocta® (efmoroctocog alfa), a recombinant human factor VIII Fc-fusion protein with an extended half-life for the treatment of haemophilia A, has been approved for reimbursement in the UK, Italy and France. These countries join Germany, Sweden, Denmark, Norway, Switzerland, the Netherlands, Slovenia and the Republic of Ireland where Elocta is already available.

This expansion in availability is supported by global experience. With more than two years of post-authorisation real-world experience with Elocta (marketed as Eloctate® in the US and other regions), over 2,700 patients have been treated in countries where Elocta is commercially available, corresponding to about 1,800 patient-years of experience.

"This extensive post approval clinical experience with Elocta complements the clinical data generated by our pivotal clinical studies, and follows the findings of the long term ASPIRE extension study. We believe that this comprehensive clinical data and real world experience can provide support to clinicians and patients while making their treatment choices as Elocta becomes available in additional countries," said Krassimir Mitchev, MD, PhD, Vice President and medical therapeutic area head of Haemophilia at Sobi.

The safety and efficacy of long-term use of the extended half-life recombinant Fc-factor VIII, Elocta for haemophilia A were highlighted in a series of oral and poster presentations by Biogen and Sobi at the World Federation of Hemophilia (WFH) 2016 World Congress in Orlando, Florida that took place 24-28 July 2016. Through the pivotal clinical trials (A-LONG, Kids A-LONG) and extension study (ASPIRE) 233 patients have been treated with Elocta. Overall clinical study experience with Elocta confirms its long term safety and efficacy, and supports its potential to offer extended protection against bleeds.

Eloctate was first approved for haemophilia A in the USA in June 2014 and in the EU (as Elocta) in November 2015.

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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.

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

About Elocta®/Eloctate®
Elocta (efmoroctocog alfa), the first recombinant clotting factor VIII therapy that offers an extended half-life in the body, is approved in the European Union, Switzerland, Iceland, Liechtenstein and Norway, as well as the United States, Canada, Australia, New Zealand and Japan (as Eloctate). It was developed for haemophilia A by fusing factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables Elocta to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Sobi and Biogen are the first companies to utilise it in the treatment of haemophilia.

As with any factor replacement therapy, development of inhibitors may occur following administration of Elocta/Eloctate.

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. 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.
[ii] Guideline for the management of hemophilia, World Federation of Hemophilia, 2nd edition, http://www1.wfh.org/publication/files/pdf-1472.pdf. Accessed December 2015