

## PRESS RELEASE

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## Elocta® obtains national reimbursement in Spain, now available in the five largest markets in the EU

[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 received national reimbursement approval in Spain. Elocta is already available in the UK, France, Italy, Germany, Sweden, Denmark, Norway, Switzerland, the Netherlands, Slovenia and the Republic of Ireland.

"This approval is an important reimbursement milestone for Elocta, representing the last of the five largest markets in the EU. Our focus is to continue our work to ensure timely access to Elocta for people living with haemophilia A in these countries and in the rest of the Sobi territory", said Geoffrey McDonough CEO and President at Sobi.

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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.<sup>i</sup> The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.<sup>ii</sup>

### 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, Brazil, Taiwan 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](http://www.sobi.com).

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**About the Sobi and Biogen Collaboration**

Sobi and Biogen collaborate on the development and commercialisation of the haemophilia products Elocta 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 and Alprolix and has final development and commercialisation rights in North America and all other regions in the world excluding the Sobi territory.

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<sup>i</sup> World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: [http://www.wfh.org/en/page.aspx?pid=637#Difference\\_A\\_B](http://www.wfh.org/en/page.aspx?pid=637#Difference_A_B). Accessed on: June 17, 2016.

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