PRESS RELEASE

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The first patient enrolled in the ReITIrate study evaluating immune tolerance induction with Elocta®

Swedish Orphan Biovitrum AB (publ) (Sobi™) announces today that the first patient has been enrolled in the open-label, multicentre ReITIrate study (NCT03103542). The ReITIrate study is designed to investigate the immune tolerance induction (ITI) potential of Elocta® (efmoroctocog alfa) in patients with haemophilia A who have developed inhibitors which have failed to be resolved with other therapies. The study is being performed under the collaboration agreement with Bioverativ Therapeutics Inc.

The development of antibodies (inhibitors) that neutralise the effect of factor VIII is one of the most serious complications to haemophilia A treatment, making standard replacement therapy ineffective, increasing the risk for severe bleeding and morbidity, decreasing quality of life and increasing health care costs[i].

“We are committed to provide treatment options to patients with haemophilia that will enable them to make choices and live the lives they would like to live. The ReITIrate study is very much aligned with that commitment and may address one of the most critical questions – treatment management of patients who have developed inhibitors,” says Krassimir Mitchev, MD, PhD, Vice President and Medical Therapeutic Area Head of Haemophilia at Sobi.

The efficacy and safety of Elocta in previously treated patients (PTPs) have been established in clinical trials and further confirmed in real-world clinical settings.

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 (WHF) estimates that approximately 150,000 people are currently diagnosed with haemophilia A world-wide[ii]

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[iii]. The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction[iv].

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 Sobi for the treatment of haemophilia A in the European Union, Switzerland, Iceland, Liechtenstein, Norway, Kuwait and Saudi Arabia. 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, where Bioverativ has the marketing rights.

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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/ELOCTATE and Alprolix.

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] Krishnamoorthy et al. *Cell Immunol.* 2016; 301:30-39

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

[iii] 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

[iv] 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