PRESS RELEASE

Stockholm, Sweden, 2 March 2017

Sobi™ receives approval from the European Medicines Agency for higher capacity drug substance manufacturing for Elocta®

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) has received approval from the European Medicines Agency (EMA) for the grouped type II 15 K Variation for Elocta® (efmoroctocog alfa). The variation involves several changes, including the approval of Elocta drug substance manufacturing in 15 000 litre scale bioreactors. Elocta is a recombinant extended half-life factor VIII Fc fusion protein product for the treatment of haemophilia A.

"Sobi is committed to providing a consistent and reliable supply of Elocta across our territories and the recent EMA approval is another important step toward fulfilling that commitment," says Philip Wood, Vice President and Commercial Therapeutic Area Head Haemophilia at Sobi. "This also supports our global commitment with Bioverativ to donate up to 1 billion international units of Elocta and Alprolix to the developing world. The companies have already donated more than 200 million international units, making thousands of treatments possible over the last 18 months in collaboration with the World Federation of Hemophilia."

Bioverativ has manufacturing responsibility for Elocta to Sobi as part of a collaboration between Sobi and Bioverativ.

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.

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Elocta is approved for the treatment of haemophilia A in the European Union, Switzerland, Iceland, Liechtenstein, Norway and Kuwait, marketed by Sobi. 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, which is marketed as ELOCTATE® in the United States, Japan and Canada. Sobi has final development and commercialization 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. 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