

## **PRESS RELEASE**

Stockholm, 21 November 2014

### **Sobi exercises opt-in right for Elocta™**

[Swedish Orphan Biovitrum](#) AB (publ) (Sobi) (STO: SOBI) announced today that the company has decided to exercise its opt-in right to take over final development and commercialisation of Elocta (rFVIII Fc) for the territory composed of Europe, North Africa, Russia and most Middle Eastern markets. Elocta/Eloctate™ is a recombinant factor VIII Fc fusion protein product candidate for the treatment of haemophilia A. Sobi will make a payment to Biogen Idec of USD 10 million, which will be held in escrow pending the EU regulatory approval of Elocta. Details about this and other compensation are described in the Collaboration Agreement section below.

“This is an important milestone for Sobi and the result of a strong collaboration between our two companies,” said Geoffrey McDonough, CEO at Sobi. “Sobi’s legacy in haemophilia and rare diseases provides a platform for making this innovative treatment available for people with haemophilia A in our territory.”

Biogen Idec and Sobi are long-time collaborators in the development and commercialisation of Elocta/Eloctate for haemophilia A. Biogen Idec leads development for Elocta/Eloctate, has manufacturing rights, and has commercialisation rights in North America and all other regions excluding the Sobi territories.

On 31 October 2014 Sobi and Biogen Idec announced that the European Medicines Agency (EMA) validated the Marketing Authorisation Application (MAA) for Elocta. The validation of the MAA initiated the EMA’s review process. Elocta is the European trade name for rFVIII Fc, also known as Eloctate [Antihemophilic Factor (Recombinant), Fc Fusion Protein] in the U.S., Canada, and Australia, where it is approved for the treatment of haemophilia A. Elocta/Eloctate is the first recombinant clotting factor VIII therapy with prolonged circulation to provide protection from bleeding episodes with the potential for an extended interval between prophylactic injections.

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#### **About Haemophilia A**

Haemophilia A is a rare, chronic, genetic disorder in which the ability of a person’s blood to clot is impaired, due to missing or reduced levels of a protein known as factor VIII. People with haemophilia A experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening haemorrhages. The World Federation of Hemophilia global survey conducted in 2012 estimates that approximately 142,000 people worldwide are identified as living with haemophilia A.

### **About Elocta/Eloctate**

Elocta/Eloctate is an investigational, recombinant clotting factor therapy 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). It is believed that this enables Elocta/Eloctate to use a naturally occurring pathway to prolong the time therapy remains in the body. While Fc fusion has been used for more than 15 years, Biogen Idec is the only company to apply it to the treatment of haemophilia.

### **About the Biogen Idec and Sobi Collaboration**

To exercise its opt-in right to take over final development and commercialization of Elocta for its territory, Sobi will now make a payment into escrow of USD 10 million. Upon EU regulatory approval of Elocta, Sobi will be liable to repay approximately half of the development and manufacturing costs for Elocta/Eloctate incurred by Biogen Idec to date (approximately USD 180 million), as well as for additional investments made until Sobi formally assumes responsibility as the Marketing Authorization Holder for Elocta. Sobi estimates the total repayment obligation to reach approximately USD 240 million.

The base royalty structure under the agreement states that Sobi will pay Biogen Idec 12% of direct sales in the Sobi territory, and Biogen Idec will pay Sobi 12% of direct sales in North America and 17% of direct sales in other markets. For Sobi to meet its repayment obligation, the base royalty structure will be adjusted during a repayment period beginning at the time of the first commercial sale in the Sobi territory, with the difference between the base royalties and the adjusted royalties being credited to Sobi's repayment obligation. According to the adjusted schedule Sobi will pay Biogen Idec a 17% royalty on direct sales in the Sobi territory, and Biogen Idec will pay Sobi a 7% royalty on direct sales in the Biogen Idec North America territory, and up to 12% in other markets. Upon complete repayment or July 2020, whichever comes sooner, the base 12% cross-royalty structure will apply.

The cross-royalty and collaboration structure is described in detail in the Sobi press release dated 2012-02-06 "[Sobi's agreement with Biogen Idec regarding long-lasting rFVIII-Fc and rFIX-Fc hemophilia programs](http://www.sobi.com/en/Investors--Media/News/RSS/?RSS=http://cws.huginonline.com/S/134557/PR/201202/1582735.xml)". (<http://www.sobi.com/en/Investors--Media/News/RSS/?RSS=http://cws.huginonline.com/S/134557/PR/201202/1582735.xml>)

### **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 Inflammation and Genetic diseases, with two late stage biological development projects within Haemophilia. Sobi also markets a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2013, Sobi had total revenues of SEK 2.2 billion (€253 M) and about 550 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at [www.sobi.com](http://www.sobi.com).

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