

## **PRESS RELEASE**

Stockholm, 16 July 2015

### **Sobi exercises opt-in right for Alprolix®**

[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 Alprolix (rFIXFc) for the territory composed of Europe, North Africa, Russia and certain Middle Eastern markets. Alprolix is a recombinant factor IX Fc fusion protein product candidate for the treatment of haemophilia B. Sobi will make a payment to Biogen of USD 10 million, which will be held in escrow pending the EU regulatory approval of Alprolix.

“This is an important milestone for Sobi and the result of a strong collaboration between Sobi and Biogen,” said Geoffrey McDonough, CEO at Sobi. “We are looking forward to the possibility of making this innovative treatment available for people with haemophilia B upon approval in our territory, increasing treatment choices and advancing patient care for the haemophilia community.”

Sobi and Biogen are collaboration partners in the development and commercialisation of Alprolix for haemophilia B. Sobi has an opt-in right to assume final development and commercialisation of Alprolix for the Sobi territory. Biogen has led development for Alprolix, has manufacturing rights, and has commercialisation rights in North America and all other regions in the world excluding the Sobi territory.

On 26 June 2015 Sobi and Biogen announced that the European Medicines Agency (EMA) had validated the Marketing Authorisation Application (MAA) for Alprolix. The validation of the MAA initiated the EMA’s review process. Alprolix [Coagulation Factor IX (Recombinant), Fc Fusion Protein] is approved for the treatment of haemophilia B in the U.S., Canada, Australia, and Japan.

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#### **About Haemophilia B**

The World Federation of Hemophilia global survey conducted in 2013 estimates that approximately 28,430 people are currently diagnosed with haemophilia B worldwide. It is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting. People with haemophilia B experience bleeding episodes that cause pain, irreversible joint damage, and life-threatening haemorrhages. Prophylactic infusions of factor IX temporarily replace clotting factors necessary to control bleeding and prevent new bleeding episodes.

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### **About Alprolix**

Alprolix is a recombinant, clotting factor therapy developed for haemophilia B by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). It is believed that this enables Alprolix to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion has been used for more than 15 years, Biogen and Sobi are the only companies to apply it in haemophilia.

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

To exercise its opt-in right to take over final development and commercialization of Alprolix for its territory, Sobi will now make a payment into escrow of USD 10 million. Upon EU regulatory approval of Alprolix, Sobi will be liable to repay approximately half of the development and manufacturing costs for Alprolix incurred by Biogen, as well as for additional investments. Sobi estimates the total repayment obligation to reach approximately USD 201 million.

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](#)".

### **About Sobi**

Sobi is an international specialty healthcare company dedicated to rare diseases. Our 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. We also market a portfolio of specialty and rare disease products for partner companies across Europe, the Middle East, North Africa and Russia. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 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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