

PRESS RELEASE

9 October, Stockholm, Sweden



Sobi's collaboration partner Biogen Idec files marketing authorisation application for Elocta™ (rFVIII Fc) in Europe

[Swedish Orphan Biovitrum AB \(publ\) \(Sobi\)](#) announced today that Biogen Idec has submitted a Marketing Authorisation Application (MAA) for Elocta (rFVIII Fc) to the European Medicines Agency (EMA). Sobi has an exclusive opt-in right to assume final development and commercialisation of Elocta in Europe, Russia, the Middle East and Northern Africa.

The MAA filing with the EMA triggers the formal opt-in right, giving Sobi approximately two months to exercise its option.

Elocta is a long-acting recombinant factor VIII Fc fusion protein product candidate for people with haemophilia A. Elocta is the approved European trade name for rFVIII Fc, also known as Eloctate™ in the U.S., Canada, and Australia, where it is approved for the treatment of hemophilia A.

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 recurrent and extended bleeding episodes that cause pain and irreversible joint damage. Some of these bleeding episodes can be life-threatening. According to the World Federation of Hemophilia, an estimated 142,000 people worldwide are identified living with haemophilia A.¹ Prophylactic injections of factor VIII can temporarily replace the clotting factor necessary to control bleeding and prevent new bleeding episodes.

About the Biogen Idec and Sobi Collaboration

Biogen Idec and Swedish Orphan Biovitrum (Sobi) are collaborators in the development and commercialisation of Elocta/Eloctate for haemophilia A. Biogen Idec leads development, has manufacturing rights, and has commercialisation rights in North America and all other regions in the world excluding the Sobi territory. Sobi has the right to opt in to assume final development and commercialisation in Europe, including Russia, the Middle East and Northern Africa.

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 Inflammation and Genetic diseases, with two late stage biological development projects within Haemophilia. We also market 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.

¹ World Federation of Hemophilia. Annual Global Survey 2012. <http://www1.wfh.org/publications/files/pdf-1574.pdf>. Accessed January 28, 2014.

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The above information was released for public distribution on 9 October 2014, at 21:00 CET.