

## PRESS RELEASE

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### The US Food and Drug Administration (FDA) approves Eloctate™<sup>1</sup>

[Swedish Orphan Biovitrum](#) AB (publ) (Sobi) partner [Biogen Idec](#) has announced that the US Food and Drug Administration (FDA) has approved Eloctate [Antihæmophilic Factor VIII (Recombinant), Fc Fusion Protein] for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with hæmophilia A. This is the first regulatory approval worldwide for Eloctate and the therapy is currently under review by regulatory authorities in several other countries including Canada, Australia and Japan.

“The FDA approval for Eloctate represents the most significant treatment advance for people with hæmophilia A in more than 20 years,” said Geoffrey McDonough, President and CEO of Sobi. “This is a major milestone in our collaboration with Biogen Idec.”

The approval of Eloctate for both adults and children is based on results from the global, phase 3 A-LONG clinical study, as well as interim pharmacokinetic and safety data from the phase 3 Kids A-LONG study.

Eloctate was developed using a process called Fc fusion and is the first recombinant hæmophilia A therapy to be approved with prolonged circulation in the body. It is the only treatment for hæmophilia A to reduce the frequency of bleeding episodes with prophylactic infusions every four days, with adjustments to every three to five days based on patient response. Eloctate offers people with hæmophilia A the potential to extend the interval between prophylactic infusions and thereby reducing the burden of treatment.

For approval in Europe, the European Medicines Agency requires the inclusion of paediatric study data in a marketing application for a new hæmophilia therapy. The successful completion of the Kids A-LONG study in April 2014 was therefore an important step to obtaining marketing authorisation in Europe. Sobi and Biogen Idec plan to file for market authorisation of the product in Europe. Sobi’s territories also include Russia, North Africa and the Middle East.

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<sup>1</sup> Eloctate is the approved US brand name for rFVIII-Fc.

Biogen Idec's press release regarding the USFDA approval of Eloctate can be found here:

[http://www.biogenidec.com/press\\_release\\_details.aspx?ID=14712&Action=1&NewsId=2338&M=NewsV2&PID=61997](http://www.biogenidec.com/press_release_details.aspx?ID=14712&Action=1&NewsId=2338&M=NewsV2&PID=61997).

#### **About Eloctate**

Eloctate (Antihaemophilic Factor (Recombinant), Fc Fusion Protein) is the first recombinant clotting factor VIII therapy with prolonged circulation in the body. In the US it is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with haemophilia A. ELOCTATE is not indicated for the treatment of von Willebrand disease. Eloctate was developed by fusing B-domain deleted factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG<sub>1</sub> (a protein commonly found in the body). It is believed that this enables Eloctate 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 Idec is the only company to apply it to the treatment of haemophilia.

Common adverse reactions (incidence of greater than or equal to 1 percent) reported in the phase 3 study of Eloctate (A-LONG) were arthralgia (joint pain) and malaise (general discomfort).

#### **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.<sup>2</sup> 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 Alprolix for haemophilia B. 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 three late stage biological development projects within Haemophilia and Neonatology. 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](http://www.sobi.com).

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<sup>2</sup> World Federation of Hemophilia. Annual Global Survey 2012. <http://www1.wfh.org/publications/files/pdf-1574.pdf>. Accessed January 28, 2014.