

## PRESS RELEASE

Stockholm, Sweden, and Cambridge, Mass., USA, 18 July 2016

### **Biogen and Sobi to showcase long-term efficacy and safety data from extended half-life haemophilia therapies at World Federation of Hemophilia 2016 World Congress**

- *Longitudinal joint health data from patients in the A-LONG, ASPIRE, B-LONG and B-YOND trials to be presented*

[Biogen](#) (NASDAQ: BIIB) and [Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi™) (STO: SOBI) will present updated data on long-term safety and efficacy of the companies' novel extended half-life therapies, Elocta® (efmoroctocog alfa) (marketed as Eloctate® in the US and other regions outside of Europe) for haemophilia A and Alprolix® (eftrenonacog alfa) for haemophilia B. The data from the phase 3 extension studies, B-YOND (haemophilia B) and ASPIRE (haemophilia A), will be highlighted in oral and poster presentations at the World Federation of Hemophilia (WFH) 2016 World Congress in Orlando, Florida, from 24-28 July 2016.

"The breadth of research, for both marketed products and preclinical programmes being presented at WFH reflects our commitment to haemophilia and our mission to improve the lives of people living with haemophilia," said Rob Peters, vice president, rare disease research at Biogen.

For people with severe haemophilia A and B, most bleeding events occur in joints, with joint damage being the most common complication of the condition.<sup>i</sup>

Post hoc analyses to be presented at the WFH Congress include longitudinal evaluation of joint health from patients participating in A-LONG and ASPIRE and target joint data from a subset of patients participating in B-LONG and B-YOND.

Additionally, preclinical pharmacokinetic data from intravenous and subcutaneous administration of recombinant FVIII-Fc-VWF-XTEN, a fusion protein being investigated for the treatment of haemophilia A, that utilises XTENTM technology licensed from Amunix, will be presented.

"Elocta and Alprolix are backed by robust clinical data and significant real-world experience. We believe these new data presentations will help healthcare providers to deepen their understanding of the clinical value and utility of these innovative medicines," said Krassimir Mitchev, MD, PhD, vice president and medical therapeutic area head of Haemophilia at Sobi.

Elocta and Alprolix are the first approved haemophilia A and B Fc fusion therapies to provide extended protection against bleeding episodes. They utilise Fc fusion technology, which uses a naturally occurring pathway to prolong the time the therapy remains in the body.

Select presentations include:

*Elocta/Alprolix-focused presentations:*

- Longitudinal Modified Haemophilia Joint Health Scores (mHJHS) Outcomes With Recombinant Factor VIII Fc Fusion Protein (rFVIII Fc) Prophylaxis in Subjects With Severe Haemophilia A – Oral Presentation # T-02 – Tuesday, 26 July, 2:55 – 3:05 EST
- Longitudinal Analysis of Annualized Bleeding Rates Among Adults/Adolescents Receiving Weekly Prophylaxis With rFVIII Fc in A-LONG and ASPIRE – Poster # P150 – Monday, 25 July, 10:00 – 10:45 & 3:45 – 4:30 EST
- Post Hoc Analysis to Evaluate the Effect of Recombinant Factor IX Fc Fusion Protein (rFIX Fc) Prophylaxis in Adults and Adolescents with Target Joints and Haemophilia B – Poster # P83 – Tuesday, 26 July, 10:00 – 10:45 EST

*Preclinical rFVIII Fc-VWF-XTEN presentation:*

- The pharmacokinetic profiles of intravenously and subcutaneously administered recombinant FVIII Fc-VWF-XTEN in cynomolgus monkey – Oral Presentation W-01 – Wednesday, 27 July, 10:45 – 11:00 EST

---

**About Haemophilia A and B**

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. Haemophilia B occurs in about one in 25,000 male births annually, and more rarely in females. Worldwide, it is estimated that more than 400,000 people are living with haemophilia.

People with haemophilia A or B experience prolonged bleeding episodes that can cause pain, irreversible joint damage and life-threatening hemorrhages. Prophylactic infusions of factor VIII or IX can temporarily replace the missing clotting factors that are needed to control bleeding and prevent new bleeding episodes.<sup>ii</sup> The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.<sup>iii</sup>

**About Elocta®/Eloctate®**

Elocta (efmoroctocog alfa), the first recombinant clotting factor VIII therapy with prolonged circulation in the body, is approved in the European Union, Switzerland, Iceland, Liechtenstein and Norway, as well as the United States, Canada, Australia, New Zealand and Japan (as Eloctate). It was 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). This enables Elocta to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Sobi and Biogen are the first companies to utilise it in the treatment of haemophilia.

Inhibitors have been reported with factor replacement therapy in the treatment of haemophilia A. Inhibitor development has been observed with rFVIII Fc (Elocta/Eloctate) in the treatment of haemophilia A, including previously untreated patients.

#### **About Alprolix®**

Alprolix® (eftrenonacog alfa) 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). This enables Alprolix to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Sobi and Biogen are the first companies to utilise it in the treatment of haemophilia.

Alprolix is currently approved for the treatment of haemophilia B in the European Union as well as Iceland, Liechtenstein and Norway, as well as the US, Canada, Japan, Australia, New Zealand. As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur following administration of Alprolix.

#### **About Biogen**

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies, and patients worldwide benefit from its leading multiple sclerosis and innovative haemophilia therapies. For more information, please visit [www.biogen.com](http://www.biogen.com). Follow us on Twitter.

#### **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 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at [www.sobi.com](http://www.sobi.com).

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

Biogen and Sobi collaborate on the development and commercialisation of Elocta and Alprolix. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Biogen has manufacturing responsibility for Eloctate and Alprolix and has final development and commercialisation rights in North America and all other regions in the world excluding the Sobi territory.

Biogen recently announced that it intends to spin off its haemophilia business as an independent, publicly-traded company. The new company will focus on meaningfully improving the treatment and care of people living with haemophilia, with existing marketed products to include Eloctate and Alprolix, indicated for the treatment of haemophilia A and B, respectively. The new company will continue to collaborate with Sobi once it is independent.

**For more information please contact**

Media relations Sobi

Oskar Bosson, Head of Communications

+46 70 410 71 80

[oskar.bosson@sobi.com](mailto:oskar.bosson@sobi.com)

Investor relations Sobi

Jörgen Winroth, Vice President, Head of Investor Relations

+1 347-224-0819, +1 212-579-0506, +46 8 697 2135

[jorgen.winroth@sobi.com](mailto:jorgen.winroth@sobi.com)

Media Contact Biogen

Todd Cooper

+1-781-464-3260

[public.affairs@biogen.com](mailto:public.affairs@biogen.com)

Investor relations Biogen:

Benjamin Strain

+1-781-464-2442

[IR@biogen.com](mailto:IR@biogen.com)

---

<sup>i</sup> Hemophilia Federation of America. Joint Damage. Available at: <http://www.hemophiliafed.org/bleeding-disorders/complications/joint-damage/>. Accessed on July 6, 2016.

<sup>ii</sup> World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: [http://www.wfh.org/en/page.aspx?pid=637#Difference\\_A\\_B](http://www.wfh.org/en/page.aspx?pid=637#Difference_A_B). Accessed on: June 17, 2016.

<sup>iii</sup> Guideline for the management of hemophilia, World Federation of Hemophilia, 2nd edition, <http://www1.wfh.org/publication/files/pdf-1472.pdf>. Besöktes i december 2015