

## PRESS RELEASE

Paris, France, 1 February 2017

### **Sobi and Bioverativ to reveal new long-term safety and efficacy data of Elocta® and Alprolix® at EAHAD**

[Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi™) and [Bioverativ Inc.](#) (NASDAQ: BIVVV) will present new haemophilia data at the 10th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD), taking place in Paris, France, 1-3 February 2017. Nine abstracts from Sobi- and Bioverativ<sup>1</sup>-led studies have been accepted for presentation during EAHAD, reflecting the companies' commitment to the haemophilia community.

The nine posters include data on the long-term safety and efficacy of the companies' extended half-life therapies, Elocta® (efmoroctocog alfa), marketed as ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] in the United States, Japan and Canada, and Alprolix® (eftrenonacog alfa), in people of all ages with haemophilia A and B, respectively, providing an updated analysis of long-term data from the registration studies ASPIRE and B-YOND.

"Sobi and Bioverativ are committed to supporting the haemophilia community to better understand the potential of extended half-life factor treatments," says Krassimir Mitchev, MD, PhD, vice president and medical therapeutic area head of Haemophilia at Sobi. "These data present how to individualise dosing and consumption in order to gain a comprehensive protection beyond prevention of bleeds."

"These data provide additional insights for physicians and people living with haemophilia, and reinforce the well-characterised safety and efficacy profile for Elocta/ELOCTATE and Alprolix. These are the only haemophilia therapies utilizing Fc fusion technology, which uses the body's natural pathway to prolong the time the therapy remains in the body," said Maha Radhakrishnan, MD, senior vice president of medical at Bioverativ.

#### *Elocta/ELOCTATE – Long-term safety and efficacy data across all age groups*

- Poster P023: Dosing Regimens Before and During Long-Term Treatment With Recombinant Factor VIII Fc Fusion Protein (rFVIII-Fc) in Children With Severe Haemophilia A: An Updated Analysis of the ASPIRE Study
- Poster P100: Dosing Regimens Before and During Long-Term Treatment With Recombinant Factor VIII Fc Fusion Protein (rFVIII-Fc) in Adults and Adolescents With Severe Haemophilia A: An Updated Analysis of the ASPIRE Study

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<sup>1</sup> Bioverativ was created as a spin-off from Biogen's hemophilia business and separated from Biogen effective February 1, 2017. Bioverativ is an independent, publicly-traded company, headquartered in Waltham, Massachusetts. Funding and support for these studies was provided by Biogen Inc. prior to Bioverativ's separation from Biogen.

### *Alprolix – Long-term safety and efficacy data across all age groups*

- Poster P108: Individualised Prophylaxis in Children With Haemophilia B Treated Long Term With Recombinant Factor IX Fc Fusion Protein (rFIXFc): Updated Interim Results of the B-YOND Extension Study
- Poster P094: Individualised Prophylaxis With Recombinant Factor IX Fc Fusion Protein (rFIXFc) in Adults/Adolescents With Haemophilia B: Updated Interim Results of the B-YOND Extension Study
- Poster P069: Long-Term Safety and Efficacy of Recombinant Factor IX Fc (rFIXFc) For Treatment of Severe Haemophilia B: European Subgroup Interim Analysis of the B-Yond Study
- Poster P088: Impact of Adherence On Outcomes of Prophylactic Treatment in Severe Haemophilia Patients

### *Further the understanding of the potential with the haemophilia treatments*

- Poster P195: The Cost-Utility Analysis of ELOCTA® (Efmoctocog Alfa) in the Swedish Setting
- Poster P098: Utilisations and Costs of Bypass Therapies For the Management of Haemophilia A Patients With Inhibitors
- Poster P086: Burden of Illness in Haemophilia Across the Life Course

Abstracts are available through the EAHAD 2017 web site, <http://eahad2017.com/>.

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### **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. The World Federation of Hemophilia estimates that approximately 180,000 people are currently diagnosed with haemophilia A and B world-wide<sup>[vii]</sup>.

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

### **About Elocta®/ELOCTATE®**

Elocta® (efmoctocog alfa), is a recombinant clotting factor therapy developed for haemophilia A with prolonged circulation in the body using Fc fusion technology. It is engineered by fusing factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling Elocta to use a naturally occurring pathway to extend the time the therapy remains in the body. While Fc fusion technology has been used for

more than 15 years, Sobi and Bioverativ have optimised the technology and are the first companies to utilise it in the treatment of haemophilia. Elocta is manufactured using a human cell line in an environment free of animal and human additives.

Elocta is approved for the treatment of haemophilia A in the European Union, Iceland, Liechtenstein, Norway, Switzerland, and Kuwait, and marketed by Sobi. In the United States, Japan, Canada, Australia, New Zealand, Brazil, and other countries, it is approved as ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein], and Bioverativ has marketing rights in these regions.

As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur in the treatment of haemophilia A. Inhibitor development has been observed with Elocta/ELOCTATE, including in previously untreated patients. For more information, please see the full [U.S. prescribing information](#) for ELOCTATE. Note that the indication for previously untreated patients is not included in the [EU Product Information](#) for Elocta.

#### **About Alprolix®**

Alprolix® (eftrenonacog alfa) [Coagulation Factor IX (Recombinant), Fc Fusion Protein], is a recombinant clotting factor therapy developed for haemophilia B using Fc fusion technology to prolong circulation in the body. It is engineered by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling Alprolix to use a naturally occurring pathway to extend the time the therapy remains in the body (half-life). While Fc fusion technology has been used for more than 15 years, Bioverativ and Sobi have optimised the technology and are the first companies to utilise it in the treatment of haemophilia. Alprolix is manufactured using a human cell line in an environment free of animal and human additives.

Alprolix is approved for the treatment of haemophilia B in the European Union, Iceland, Liechtenstein, Norway and Switzerland, and marketed by Sobi. It is also approved in the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries, and Bioverativ has marketing rights in these regions.

Allergic-type hypersensitivity reactions and development of inhibitors have been observed with Alprolix in the treatment of haemophilia B, including in previously untreated patients. For more information, please see the full [U.S. prescribing information](#) for Alprolix. Note that the indication for previously untreated patients is not included in the [EU Product Information](#).

#### **About Bioverativ**

Bioverativ (NASDAQ: BIVV) is a global biotechnology company dedicated to transforming the lives of people with haemophilia and other rare blood disorders through world-class research, development and commercialisation of innovative therapies. Launched in 2017 following separation from Biogen Inc., Bioverativ builds upon a strong heritage of scientific innovation and is committed to actively working with the blood disorders community. The company's mission is to create progress for patients where they need it most and its haemophilia therapies, when launched, represented the first major advancements in haemophilia treatment in more than two decades. For more information, visit [www.bioverativ.com](http://www.bioverativ.com) or follow @bioverativ on Twitter. Beginning tomorrow, February 2, 2017, the company will trade on the NASDAQ Global Select Market under the ticker symbol "BIVV."

Bioverativ was created as a spin-off from Biogen's hemophilia business and separated from Biogen effective February 1, 2017. Bioverativ is an independent, publicly-traded company, headquartered in Waltham, Massachusetts. During a temporary transition period, which includes time to allow Bioverativ to establish certain licenses and consents related to ELOCTATE and ALPROLIX, each of Bioverativ and Biogen will have a relationship to the products.

### 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 Bioverativ and Sobi collaboration

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

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[vii] World Federation of Hemophilia, Annual Global Survey 2015, published in October 2016. Available at: <http://www.wfh.org/en/data-collection>

[viii] 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.

[ix] Guideline for the management of hemophilia, World Federation of Hemophilia, 2nd edition, <http://www1.wfh.org/publication/files/pdf-1472.pdf>. Accessed on December 2015