

PRESS RELEASE

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Sobi and Bioverativ highlight commitment to improving care for people with haemophilia at ISTH 2017 congress

New data on joint health, immune tolerance induction, and long-term quality-of-life outcomes underscore the companies' dedication to addressing unmet needs in haemophilia treatment and care.

[Swedish Orphan Biovitrum AB](#) (publ) (Sobi™) (STO: SOBI) and [Bioverativ Inc.](#) (NASDAQ: BIVV) today announces that new data from their extended half-life therapies, Alprolix® (eftrenonacog alfa) ([Coagulation Factor IX (Recombinant), Fc Fusion Protein] and Elocta® (efmoroctocog alfa), marketed as ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein]) in the United States, Japan and Canada, will be presented at the International Society on Thrombosis and Haemostasis (ISTH) 2017 Congress, taking place in Berlin, Germany, from July 8-13, 2017.

Researchers and investigators will present updated analyses of long-term follow-up data from the ASPIRE and B-YOND extension studies in adults, adolescents and children, further supporting the existing safety and efficacy of Alprolix and Elocta. Data from the first and only longitudinal study of joint health in patients treated prophylactically with extended half-life therapies will also be presented. These data and the additional findings reported on joint health and long-term quality-of-life outcomes reflect the companies' commitment to addressing areas of unmet need in haemophilia.

"Debilitating joint disease is a common and challenging complication for people with haemophilia," said Maha Radhakrishnan, MD, Senior Vice President of Medical at Bioverativ. "New data supporting Elocta's and Alprolix's impact on long-term joint health when used prophylactically will be presented at ISTH, and reflect our continued focus on improving the care and clinical outcomes for people living with haemophilia."

Most bleeding events for people with severe haemophilia A and B occur in joints, with joint damage being the most common complication of the condition.¹ Data presented at ISTH will demonstrate improvements in modified haemophilia joint health scores, low target joint annualised bleeding rates (ABRs) and target joint resolution for people receiving prophylactic treatment with Alprolix and Elocta. The long-term safety and efficacy of these products will also be presented at the congress.

"New data will reinforce that Elocta and Alprolix treatment can maintain low ABRs, therefore helping improve the long-term quality-of-life for people with haemophilia A and B," said Krassimir Mitchev, MD, PhD, Vice President and Medical Therapeutic Area Head of Haemophilia at Sobi. "Based on haemophilia-related quality-of-life measures, findings will show that improvements were seen in patients utilising these therapies

over several years, with the most pronounced improvement in areas including physical health and sports and leisure.”

The development of inhibitors to factor replacement therapy is one of the most serious complications for people with haemophilia, and immune tolerance induction (ITI) treatment can represent a significant burden for patients and their quality of life. A retrospective chart analysis (US and Canada) on ELOCTATE used for ITI in severe haemophilia A patients with inhibitors will also be discussed in a late-breaking poster presentation.

Symposium:

In addition to the data being presented at the Congress, Sobi and Bioverativ will co-host a company-sponsored scientific symposium, “Fc extended half-life recombinant factor concentrates: Recent updates on haemophilia management and treatment goals” on July 10 at 13:15–14:30 CEST. Supported by global patient case reports, the session will focus on features of Fc fusion factors, evolving technologies and methodologies in haemophilia management, plus real world experience with initiating and continuing treatment with Elocta/ELOCTATE and Alprolix and their impact on long-term treatment goals.

Presentation highlights include:

Immune Tolerance Induction Late-breaking Abstract

- rFVIII-Fc For Immune Tolerance Induction in Severe Haemophilia A Patients With Inhibitors – A Retrospective Analysis – Poster LB 04 - Monday, July 10 from 12:00 – 13:15 CEST

Joint Health-Focused Abstracts

- Long-Term Impact of rFVIII-Fc Prophylaxis in Paediatric, Adolescent, and Adult Subjects with Target Joints and Severe Haemophilia A – Poster #212 – Monday, July 10, 12:00-13:15 CEST
- Longitudinal Modified Haemophilia Joint Health Scores (mHJHS) in Children, Adolescents, and Adults with Severe Haemophilia A With Long-term rFVIII-Fc Prophylaxis – Poster #946 – Tuesday, July 11, 12:00-13:15 CEST
- Target Joint Outcomes with Prophylaxis with rFIX-Fc in Adults and Adolescents with Haemophilia B: Updated Results from B-YOND – Poster #961 – Tuesday, July 11, 12:00-13:15 CEST

Quality-of-Life Outcomes-Focused Abstracts

- Long-Term Quality-of-Life Outcomes with rFIX-Fc in Adults with Haemophilia B: Results from B-LONG and B-YOND – Poster #968 – Tuesday, July 11, 12:00-13:15 CEST
- Long-Term Quality-of-Life Outcomes with rFVIII-Fc Prophylaxis in Adult Subjects with Severe Haemophilia A – Poster #1783 – Wednesday, July 12, 12:00-13:15 CEST

Long-Term Efficacy and Safety-Focused Abstract

- Efficacy and Safety of rFVIII-Fc Prophylaxis in Pediatric, Adolescent, and Adult Subjects with Severe Haemophilia A Over 3-4 Years: The ASPIRE Study – Poster #1774 – Wednesday, July 12, 12:00-13:15 CEST

Abstracts are available through the [ISTH 2017 web site](#).

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 28,000 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-wideⁱ.

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 episodesⁱⁱ. The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destructionⁱⁱⁱ.

About Elocta®

Elocta® (efmoroctocog alfa) is a recombinant clotting factor therapy developed for haemophilia A using Fc fusion technology to prolong circulation in the body. 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, Switzerland, Iceland, Liechtenstein, Norway, Kuwait and the Kingdom of Saudi Arabia, marketed by Sobi. It is approved and marketed as ELOCTATE® by Bioverativ in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, 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 optimized the technology and are the first companies to utilize 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 and marketed by Bioverativ for the treatment of haemophilia B in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, and Bioverativ has marketing rights in these regions. It is also authorised in the European Union, Iceland, Liechtenstein, Norway and Switzerland, where it is marketed by Sobi.

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 the Sobi™ and Bioverativ collaboration

Sobi and Bioverativ collaborate on the development and commercialisation of Alprolix® and Elocta, which is marketed as ELOCTATE® in the United States, Japan and Canada. Sobi has final development and commercialization rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). 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 Elocta and Alprolix.

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 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

About Bioverativ

Bioverativ is a global biotechnology company dedicated to transforming the lives of people with hemophilia and other rare blood disorders through world-class research, development and commercialization 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 hemophilia therapies when launched represented the first major advancements in hemophilia treatment in more than two decades. For more information, visit www.bioverativ.com or follow @bioverativ on Twitter.

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ⁱ World Federation of Hemophilia. Annual Global Survey 2015, published in October 2016. Available at: <http://www1.wfh.org/publication/files/pdf-1669.pdf>. Accessed on May 23, 2017.

ⁱⁱ World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: <http://www.wfh.org/en/page.aspx?pid=637>. Accessed on May 23, 2017.

ⁱⁱⁱ World Federation of Hemophilia. Guideline for the management of hemophilia, 2nd edition. Available at: <http://www1.wfh.org/publication/files/pdf-1472.pdf>. Accessed on May 23, 2017.