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Sobi emphasises commitment to haemophilia community at WFH 2018 World Congress

Recent data show quality-of-life improvements for patients treated prophylactically with Elocta® and Alprolix®, extended half-life haemophilia therapies.

Swedish Orphan Biovitrum AB (publ) (Sobi™)(STO:SOBI) will present data at the World Federation of Hemophilia (WFH) 2018 World Congress, in Glasgow, Scotland, 20-24 May, demonstrating the company's ongoing commitment to transforming the standard of care for people with haemophilia.

Sobi will present real-world data demonstrating improvements in quality-of-life measures, including physical activity and joint pain, in patients treated prophylactically with Elocta (efmoroctocog alfa) for haemophilia A and Alprolix (eftrenonacog alfa) for haemophilia B, when compared with standard half-life factor treatments. Elocta and Alprolix are extended half-life haemophilia therapies with well-established safety and efficacy profiles and close to four years of real-world experience, supported by a growing body of real-world evidence from thousands of patients across all age groups.

"We continue to advance our scientific understanding of our therapies' impact on disease burden," said Armin Reininger, Senior Vice President, Head of Medical and Scientific Affairs at Sobi. "By gathering data on outcomes such as physical activity and joint health status, we maintain our focus on research that reflects a meaningful difference for patients, providing protection beyond bleed prevention. The real-world data generated thus far support the safety profile of our products. Since both products are indicated for all age groups, in prophylaxis, on-demand as well as in surgery, they also provide the opportunity for individualised treatment."

Sobi will present a total of four abstracts including a joint presentation with Bioverativ Inc., a Sanofi company:

Sobi presentations

- Patient Reported Outcomes on Ways to Improve Haemophilia Care: Results from the CHESS Study: Wednesday, 23 May, 15:45-16:30. Poster #78
- The effect of switching to rFVIIIFc on treatment patterns and annualised bleed rate before and after: a within-patient comparison from the UK National Haemophilia Database: Wednesday, 23 May, 16:30-18:00. Oral presentation

Do EHL products meet patients' expectations (the HOPE study): Tuesday, 22 May, 16:30-18:00. Oral presentation

Sobi and Bioverativ – joint presentation

Economic impact of recombinant factor VIII Fc fusion protein (rFVIIIFc) compared to conventional factor VIII for immune tolerance induction (ITI) of Hemophilia A patients with inhibitors. Monday, 21 May, 16:30-18:00. Poster presentation #77

All oral and poster presentations can be accessed at the WFH 2018 World Congress websitehere.

In addition, Sobi and Bioverativ will co-host two scientific symposiums at the congress.

- Advances in Haemophilia: Factor-Based Therapies and Long-Term Evidence versus New Treatment Modalities. Monday, 21 May, 18:15 – 19:45, Hall 3, Scottish Event Campus. The session will be chaired by K. John Pasi, Professor, MD, PhD, Barts and the London School of Medicine and Dentistry, London and will be open to healthcare practitioners only.
- Inhibitor Eradication: Clinician and Patient Perspectives on Safety Considerations and Long-Term Outcomes. Tuesday, 22 May, 12:30-14:00, Hall 2, Scottish Event Campus. The session will be chaired by Victor Blanchette, MD, MA, MB, Pediatric Thrombosis and Hemostasis Program, The Hospital for Sick Children, Toronto and is open to all congress attendees.

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 (half-life). Elocta is manufactured using a human cell line in an environment free of animal and human additives.

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

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, 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), 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). Alprolix is manufactured using a human cell line in an environment free of animal and human additives.

Alprolix is approved and marketed by Sobi for the treatment of haemophilia B in the EU, Iceland, Kuwait, Liechtenstein, Norway, Saudi Arabia and Switzerland, as well as in the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries where Bioverativ has the marketing rights.

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 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 Haemophilia estimates that approximately 180,000 people are currently diagnosed with haemophilia A and B worldwide.[i]

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

About the Sobi and Bioverativ collaboration

Sobi and Bioverativ, a Sanofi company, collaborate on the development and commercialisation of Alprolix and Elocta/ELOCTATE. Sobi has final development and commercialisation 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/ELOCTATE and Alprolix. 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. In 2014, Sobi added the rFVIIIFc-XTEN-vWF fusion molecule for potential treatment of haemophilia A, to the collaboration agreement.

About Sobi™

Sobi™ is an international speciality healthcare company dedicated to rare diseases. Our vision is to be recognised as a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases. The product portfolio is primarily focused on treatments in Haemophilia and Specialty Care. Partnering in the development and commercialisation of products in specialty care is a key element of our strategy. Sobi has pioneered in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2017, Sobi had total revenues of SEK 6.5 billion and approximately 850 employees. The share (STO:SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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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.

SOBI
Rare Diseases
haemophilia
alprolix
elocta
Related files:
wkr0006-2925961.pdf

> rmin Reininger, Senior Vice President, Head of Medical and Scientific Affairs By gathering data on outcomes such as physical activity and joint health status, we maintain our focus on research that reflects a meaningful difference for patients, providing protection beyond bleed prevention. The real-world data generated thus far support the safety profile of our products. Since both products are indicated for all age groups, in prophylaxis, on-demand as well as in surgery, they also provide the opportunity for individualised treatment.