

## PRESS RELEASE

Stockholm, Sweden, 25 June 2019

### **Sobi presents study data supporting increased possibilities and improved clinical outcomes for people with haemophilia at ISTH**

[Sobi™](#) presents data at the ISTH 2019: The 27th Congress of the International Society on Thrombosis and Haemostasis, Melbourne, Australia, 6 – 10 July 2019, focusing on the use of Elocta® and Alprolix® in clinical settings such as treatment switches from on demand to prophylaxis and immune tolerance induction (ITI). The reported outcomes include annualised bleeding rates, quality of life as well as joint health. It will be the first time interim results from the global, prospective verITI-8 study of rFVIII Fc for first-time ITI will be presented. We will also present data showing the pain and mental burden associated with haemophilia in the real world setting.

“Previous communications have focused on the safety and efficacy of our products. Now we take one step further and show how our products can help to raise the standard of care in various situations in life, liberating life and expanding the possibilities for people with haemophilia,” says Armin Reininger, Head of Medical and Scientific Affairs at Sobi. “By increasing the scientific evidence and the understanding of the clinical value of our extended half-life products in all patient groups living with haemophilia, we maintain our focus on research and an approach to treatment that reflects a meaningful difference for patients, allowing them to live a life beyond haemophilia”.

#### **Abstracts:**

- A Survey of Physicians' Treatment Switching Practice in Long-term Prophylaxis for People with Haemophilia B in five European Countries: Sunday 7 July, Poster # PB0208
- Improved Hemostasis and Joint Health over Time in a Subset of Patients who Did Not Reach Optimal Hemostatic Control in the First Year of Recombinant Factor VIII Fc Fusion Protein (rFVIII Fc) Therapy: Sunday 7 July, Poster # PB0234. Joint with Sanofi Genzyme
- rFVIII Fc for First-time Immune Tolerance Induction (ITI) Therapy: Interim Results from the Global, Prospective verITI-8 Study: Monday 8 July. Oral Communication Session: Hemophilia Clinical 1; 10:45-12:00, Presentation # OC 32.1. Joint with Sanofi Genzyme
- People with Haemophilia and Female Carriers in Sweden have a Higher Risk of Developing Anxiety, Depression and Pain Based on Treatment Patterns as Compared to Matched Controls: Data from a Registry Study over a Period of 11 Years: Monday 8 July. Oral Communication Session: Hemophilia Clinical 1; 10:45-12:00, Presentation # OC 32.3
- A Survey of Physicians' Treatment Switching Practice in Long-term Prophylaxis for People with Haemophilia A in Five European Countries: Monday 8 July, Poster # PB0692

- Long-term Outcomes after Switch from On-demand Treatment to Prophylaxis with rFIXFc: Longitudinal Subgroup Analysis of the B-LONG and B-YOND Study Population: Monday 8 July, Poster # PB0693. Joint with Sanofi Genzyme
- Long-term Outcomes after Switch from On-demand Treatment to Prophylaxis with rFVIII Fc: Longitudinal Subgroup Analysis of the A-LONG and ASPIRE Study Population: Tuesday 9 July, Poster # PB1410. Joint with Sanofi Genzyme

All abstracts can be accessed via [the official ISTH website](#).

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#### **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 Sanofi in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, where Sanofi 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 and ITI treatment 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. It is also approved in the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries where Sanofi 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 190,000 people are currently diagnosed with haemophilia A and B worldwide.<sup>i</sup>

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.<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 the Sobi and Sanofi collaboration**

Sobi and Sanofi 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). Sanofi 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 Sanofi have optimised the technology and are the first companies to utilise it in the treatment of haemophilia. In 2014, Sobi added the rFVIII-Fc-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](http://www.sobi.com).

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<sup>i</sup> The WFH Annual Global Survey 2017 <https://www.wfh.org/en/data-collection>

<sup>ii</sup> 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.

<sup>iii</sup> 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.