

PRESS RELEASE

Stockholm, Sweden, 1 February 2021

Sobi showcases commitment to haemophilia community at EAHAD 2021

[Sobi™](#) will present data at the 14th European Association of Haemophilia and Allied Disorders (EAHAD) virtual conference from 3-5 February 2021, showing evidence further supporting the safety, efficacy and long-term benefits of its Fc-fusion extended half-life (EHL) products for the treatment of haemophilia. The data to be presented also support Sobi's ongoing commitment to liberating life for people with haemophilia now and in the future, with a new product candidate in development.

Sobi will also host a satellite symposium exploring the full potential of proactive haemophilia management to elevate expectations in people with haemophilia, including achieving and sustaining the desired level of physical activity for all ages. The discussion will also cover the value of technology and telemedicine in treatment management as well as making the right treatment choice to overcome challenges with comorbidities.

Satellite symposium:

- *Discover the Full Potential of Proactive Haemophilia Management.* 3 February, 18.00-19.00 CET. Intended for healthcare professionals only.

Oral presentation: SESSION 7 - SLAM; Friday 5 February, 14.00 - 15.00 CET

- People with haemophilia including female carriers in Nordic countries die at an earlier age and have significant co-morbidities #ABS155

ePoster presentations

- Physiologically based pharmacokinetic (PBPK) model to characterize BIVV001 activity, a new class of factor VIII (FVIII) with high sustained factor activity #ABS037
- Efficacy of RFIXFC vs RIX-FP for the treatment of patients with haemophilia B: matching-adjusted indirect comparison of B-LONG and PROLONG-9FP TRIALS #ABS092
- Improvement in pain and levels of physical activity in patients treated with RFIXFC: post-hoc analysis of B-LONG #ABS127
- Improvement in pain-related quality of life in patients with haemophilia A treated with RFVIIIIFC individualized prophylaxis: post-hoc analysis from A-LONG #ABS128
- Interim data from a chart review study of patients with haemophilia A with inhibitors treated with recombinant factor VIII FC fusion protein (RFVIIIIFC) for immune tolerance induction #ABS136
- Ongoing validation of a new disease-specific instrument assessing functional abilities in patients with haemophilia: the hemophilia functional ability scoring tool (Hemo-Fast) #ABS149

- Rationale and study design for a prospective 48-month, multi-centre, observational study evaluating long-term effectiveness of RFVIIIIFC on joint health – the A-MORE study #ABS169
- Real-world effectiveness and usage of recombinant factor IX FC fusion protein (RFIXFC) for management of major/minor surgeries in patients with haemophilia B (HB) in France: results from the ongoing B-SURE study #ABS175
- Real-world experience of switching from SHL-RFIX to EHL-RFIXFC in moderate and severe haemophilia B patients: A retrospective analysis from two Belgian centers #ABS180

About Sobi™

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,500 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi's revenues amounted to SEK 14.2 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at sobi.com.

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, UK, 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 US 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, UK, 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 BIVV001

BIVV001 (rFVIII_{FC}-VWF-XTEN) is a novel and investigational recombinant factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for people with hemophilia A. BIVV001 builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to potentially extend its time in circulation. It is the first therapy that has been shown to break through the von Willebrand factor ceiling, which is believed to impose a half-life limitation on current factor VIII therapies. BIVV001 was granted orphan drug designation by the US Food and Drug Administration in August 2017 and the European Commission in June 2019.

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 September 2019, Sobi exercised early opt-in for the development and commercialisation of BIVV001, an investigational factor VIII therapy with the potential to provide extended protection from bleeds with once-weekly dosing for people with haemophilia A.

For more information please contact

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