

PRESS RELEASE

Stockholm, Sweden, 17 June 2024



Sobi to present new haemophilia data at ISTH 2024

Sobi® will present new scientific data related to haemophilia at ISTH 2024, the 32nd Congress of the International Society on Thrombosis and Haemostasis. This event, taking place from 22nd to 26th June, will be held both online and in Bangkok. Seven abstracts have been accepted for presentation (three posters and four oral). New long-term safety and efficacy data on efanesoctocog alfa and long-term efficacy data on Elocta will be presented further demonstrating Sobi's commitment to advancing standards of care in haemophilia A treatment.

"We are pleased to present new data at this year's ISTH regarding the impact of efanesoctocog alfa on joint-health, perioperative management and long-term outcomes of keeping the patient in the non-haemophilia range for most of the week," said Lydia Abad-Franch, MD, Head of R&D and Medical Affairs, and Chief Medical Officer at Sobi. "These positive study outcomes highlight Sobi's commitment to engaging in collaborative research to support the community and improve care for people with haemophilia around the world."

Key data to be presented at ISTH 2024

Haemophilia		
Efanesoctocog alfa – Sobi/Sanofi	Interim analysis of joint outcomes in adult and adolescent patients with severe haemophilia A receiving efanesoctocog alfa during the phase 3 XTEND-ed long-term extension study	Oral Presentation. #OC 01.4 22 June 13:00 – 14:15 ICT
Efanesoctocog alfa – Sobi/Sanofi	Perioperative management with efanesoctocog alfa in adults, adolescents, and children with severe haemophilia A in the phase 3 XTEND clinical program	Oral Presentation. #OC 14.1 23 June 09:30 - 10:45 ICT
Efanesoctocog alfa – Sobi/Sanofi	Long-term outcomes with efanesoctocog alfa prophylaxis for previously treated children with severe haemophilia A, an interim analysis of the phase 3 XTEND-ed study	Oral Presentation #OC 50.2 25 June 09:45 - 10:00 ICT
Efanesoctocog alfa – Sobi/Sanofi	First interim analysis of clinical outcomes in adults and adolescents with severe haemophilia A receiving efanesoctocog alfa prophylaxis in XTEND-ed, a phase 3 long-term extension study	Oral Presentation. #OC 50.1 25 June 09:30 - 10:45 ICT
Elocta®/Eloctate® (efmoroctocog alfa) – Sobi	Long-term joint health outcomes with a recombinant factor VIII Fc from the 48-month prospective, observational A-MORE study: Third interim analysis of up to 24 months	Poster presentation. #PB0505 24 June 13:45 - 14:45 ITC
Elocta®/Eloctate® (efmoroctocog alfa) – Sobi	Effectiveness and safety of efmoroctocog alfa (a recombinant factor VIII Fc) across body mass index (BMI) categories: Pooled data from two non-interventional phase 4 studies (A-SURE/PREVENT)	Poster presentation. #PB0209 23 June 13:45 - 14:45 ITC
General Haemophilia	Using the <i>Hemophilia Functional Ability Scoring Tool</i> (Hemo-FAST) to describe the joint health status in adults with hemophilia	Poster presentation. #PB1227 25 June 13:45 - 14:45 ITC

All abstracts are accessible through the official ISTH website. However, any late-breaking abstracts will only be made available later.

About Elocta®/Eloctate®

Elocta®/Eloctate® (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, the 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, Canada Japan, Australia, New Zealand and other countries, where Sanofi has the marketing rights.

About efanesoctocog alfa

Efanesoctocog alfa [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein] (formerly BIVV001) is a high-sustained FVIII recombinant factor VIII therapy with the potential to sustain FVIII levels in non-haemophilia range (>40%) for a significant part of the week, improving bleed protection in a once-weekly dose for people with haemophilia A. Efanesoctocog alfa builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN® polypeptides to extend its time in circulation. It is the only therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on current factor VIII therapies. It is approved and marketed as ALTUVIIIIO™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] by Sanofi in the United States, Japan, and Taiwan. The European Commission granted Orphan Drug designation in June 2019. The Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive opinion recommending approval of efanesoctocog alfa for the treatment and prevention of bleeds and perioperative prophylaxis in haemophilia A in April 2024.

About the Sanofi and Sobi collaboration

Sobi and Sanofi collaborate on the development and commercialisation of Alprolix® and Elocta®/Eloctate®. The companies also collaborate on the development and commercialisation of efanesoctocog alfa, or ALTUVIIIIO™ in the US. 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.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the centre of our ambitions. Sanofi is listed on Euronext: SAN and NASDAQ: SNY

About Sobi®

Sobi® is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology, and specialty care, Sobi has approximately 1,800 employees across Europe, North America, the Middle East, Asia, and Australia. In 2023, revenue amounted to SEK 22.1 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn.

Contacts

For details on how to contact the Sobi Investor Relations Team, please click [here](#). For Sobi Media contacts, click [here](#).