PRESS RELEASE

Stockholm, Sweden, 13 July 2022

New real-world data shows significantly improved prophylactic effectiveness in patients treated with Elocta compared with standard half-life factor VIII

Annualised bleed rate (ABR), injection frequency and factor consumption were significantly lower compared to standard half-life (SHL) FVIII prophylaxis

Results demonstrated the superior prophylactic effectiveness profile of Elocta vs SHL FVIII when used in a real-world setting

A-SURE is the largest prospective, non-interventional study on the effect of extended half-life factors in haemophilia A, and directly compared Elocta with SHL factors

Positive results from the A-SURE study were presented at the 30th International Society on Thrombosis and Haemostasis (ISTH) Congress in London, demonstrating improved prophylactic effectiveness in Elocta® (efmoroctocog alfa) treated patients compared to a matched treatment group on SHL FVIII treatments. A-SURE was a 24-month prospective, non-interventional, European multi-centre study including more than 350 participants in 45 centres and the largest directly comparative study in people with haemophilia A (PwHA). The results were presented orally by Professor Johannes Oldenburg, the study principal investigator.

“The results show Elocta to be significantly superior to SHL FVIII treatments on all three endpoints,” said Professor Johannes Oldenburg, Chairman and Director of the Institute of Experimental Haematology and Transfusion Medicine and the Haemophilia Centre at the University Clinic in Bonn, Germany. “Additionally, the direct comparative head-to-head study design of A-SURE in a real-world setting is unique in haemophilia and provides a new and robust addition to making confident treatment decisions on the basis of outcomes.”

The A-SURE study was designed with a matched control group in a prospective observational study and provided well-balanced and comparable study groups (Elocta vs SHL FVIII). Median age was 24.0 (Interquartile range (IQR) 12 - 41) years and 25.5 (IQR 12 - 41) years, respectively. Almost all patients had severe haemophilia (94.1% and 97.1%, respectively) and all patients had been on prophylaxis with a FVIII product for at least 12 months prior to enrolment. Results showed statistically significant improvements in all three primary endpoints; mean ABR (1.5 vs 2.3), annualised injection frequency (114 vs 169) and annualised FVIII consumption (243,000 vs 289,000 IU), for participants treated with Elocta compared to the SHL FVIII during a 24-month prospective period. Elocta was well tolerated, consistent with the established safety profile. No inhibitors occurred, including in patients with a previous inhibitor history.

"These new data further expand the already extensive body of evidence supporting Elocta’s potential to elevate protection for people with haemophilia A,” said Anders Ullman, Head of R&D and Chief Medical Officer of Sobi. “We remain committed to continuously strengthening evidence for the treatment of haemophilia through clinical data and real-world outcomes."

About haemophilia A

Haemophilia A is a rare, genetic disorder in which the ability of a person’s blood to clot is impaired due to a lack of factor VIII. Haemophilia A occurs in about one in 5,000 male births annually, and more rarely in females. People with haemophilia can experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening haemorrhages. Factor replacement therapy remains a cornerstone of care and can be used across multiple treatment scenarios.

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About the A-SURE study
A-SURE (NCT02976753) was a 24-month prospective, non-interventional, European multicentre study in PwHA directly comparing Elocta prophylaxis with standard half-life (SHL) FVIII prophylaxis. Considering different aims for prophylactic regimens, three primary endpoints were defined, including annualised bleeding rate, injection frequency, and factor consumption. Each included patient on Elocta was matched by age and last prescribed weekly SHL FVIII dose prior to baseline at local site level to a patient on SHL FVIII. To reduce potential effects of confounding, propensity scores were estimated based on patient characteristics at baseline and adjusted for in the statistical analysis. All primary endpoints were analysed with Generalised Linear Mixed Models.

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, Brazil and other countries, where Sanofi has the marketing rights.

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, an investigational factor VIII therapy with the potential to provide high sustained factor activity levels with once-weekly dosing for people with haemophilia A. 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.

Sobi®
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Providing sustainable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East and Asia. In 2021, revenue amounted to SEK 15.5 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

Contacts
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