PRESS RELEASE

Stockholm, Sweden, 8 July 2020

Data to be presented at ISTH Virtual Congress highlights Sobi´s commitment to advancing rare haematology treatments

Sobi™ will present data at the ISTH Virtual Congress (International Society on Thrombosis and Haemostasis), 12 – 14 July 2020, strengthening evidence for the efficacy and safety of Elocta® (efmoroctocog alfa) and Alprolix® (eftrenonacog alfa), for haemophilia A and B respectively, as well as pharmacokinetic data on BIVV001 (rFVIIIFc-VWF-XTEN). Data for Doptelet® (avatrombopag) in treatment for thrombocytopenia within Chronic Liver Disease (CLD) and Chronic Immune Thrombocytopenia (ITP) will be presented.

Final data in previously untreated patients with haemophilia

Final data from the long-term studies: PUPs A-LONG and PUPs B-LONG in previously untreated patients (PUP) with haemophilia A and B, treated with Elocta and Alprolix will be presented in collaboration with Sanofi. Factor replacement therapy remains a cornerstone of haemophilia management and data shared in presentations will add to a growing body of clinical evidence for rFVIIIFc and rFIXFc, extended half-life factor therapies for haemophilia A and B, respectively.

Oral Communication

- Final results of the PUPs A-LONG Study: Evaluating Safety and Efficacy of rFVIIIFc in Previously Untreated Patients with Haemophilia A. Oral communication #OC 03.2. Sunday, July 12, 2020 from 10:15 – 11:30 EDT (16.15-17.30 CET) (Joint with Sanofi)

Abstracts

- Final Results of PUPs B-LONG Study: Evaluating Safety and Efficacy of rFIXFc in Previously Untreated Patients with Haemophilia B. Poster presentation # PB0956. (Joint with Sanofi)
- A French Multicentre Prospective, Non-Interventional Study (B-SURE) Evaluating Real-World Usage and Effectiveness of Recombinant Factor IX Fc Fusion Protein (rFIXFc) in People with Haemophilia B: Baseline Data. Poster presentation # PB0889
- Rationale and Study Design for a Prospective, Low-Interventional Study to Investigate whether Systematic Joint Examination Impacts Haemophilia Treatment Management Decisions in Patients with Haemophilia A in France: The A-MOVE Study. Poster presentation # PB0910
- No Relapse in Patients with Previous Inhibitors Switched to rFVIIIFc in Ongoing Observational Phase 4 Studies. Poster presentation # PB0936

- Females with Haemophilia in Nordic Countries Have a Higher Risk of Developing Pain, Anxiety and Depression Based on Treatment Patterns as Compared to Matched Controls: Data from a Registry Study over a Period of 11 Years. Poster presentation # PB0951
- First Interim Analysis of a 24-Month, Prospective, Non-Interventional, Multicentre Study in Germany Evaluating the Real-World Usage and Effectiveness of rFVIIIFc and rFIXFc in Patients with Haemophilia A or B (PREVENT). Poster presentation # PB0952
- Treatment-Based Risk Assessment of Developing Pain, Anxiety, and Depression as Compared to Matched Controls in People with Haemophilia. A Nordic Registry Study Over a Period of 11 Years. Poster presentation # PB0955

Potential for near-normal factor levels

Pharmacokinetic data will be presented on BIVV001, the first investigational von Willebrand (VWF)-independent factor VIII therapy designed to provide high sustained factor levels in a once-weekly dose for patients with haemophilia A. BIVV001 is being developed in collaboration with Sanofi and its molecular design offers the potential for near-normal factor levels for the majority of the week.

- Population pharmacokinetic (PK) analysis of BIVV001 (rFVIIIFc-VWF-XTEN), a new class of factor VIII (FVIII) replacement. Poster Presentation # PB0949. (Joint with Sanofi)

Data presented for the treatment of thrombocytopenia

In addition, Sobi will present data within the broader area of haematology with six abstracts involving the use of Doptelet in CLD (CLD currently approved by EMA and FDA) and ITP (ITP currently approved by FDA).

Abstracts

- Achieving Clinically Relevant Platelet Count Response Thresholds with Avatrombopag (AVA) in Immune Thrombocytopenia (ITP). Poster presentation #PB1335
- Response to Avatrombopag (AVA) in Chronic Immune Thrombocytopenia: Alternative Efficacy Measures. Poster presentation # PB1349
- Pharmacokinetic/Phamacodynamic (PK/PD) Modeling Providing Guidance for Selecting Avatrombopag (AVA) Dose When Switching from Eltrombopag in Chronic Immune Thrombocytopenia (ITP). Poster presentation # PB1350
- Pooled Safety Analysis of Avatrombopag (AVA) from Clinical Trials. Poster presentation # PB1352
- Stability of Crushed Avatrombopag Tablets Demonstrated in Multiple Food Vehicles. Poster presentation # PB1353

- Corticosteroid Reduction or Discontinuation after Initiation of Avatrombopag Treatment in Patients with Chronic Immune Thrombocytopenia (ITP). Poster presentation # PB1378

All abstracts can be accessed via the official ISTH website.

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, Norway, Liechtenstein, Switzerland, Kuwait and Saudi Arabia. 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. 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. 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 (rFVIIIFc-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 haemophilia A. BIVV001 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 is believed to impose a half-life limitation on current factor VIII therapies. BIVV001 is being developed and commercialized in collaboration with Sanofi. BIVV001 was granted orphan drug designation by the US Food and Drug Administration in August 2017 and the European Commission in June 2019. BIVV001 is currently under clinical investigation and has not been evaluated by any regulatory authority.

About Doptelet®

Doptelet® (avatrombopag) is an oral thrombopoietin (TPO) receptor agonist administered with food. Doptelet is approved by both the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) for treatment of thrombocytopenia (low platelet counts) in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. In June 2019, Doptelet was approved for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment by FDA. Chronic ITP is a rare autoimmune bleeding disorder characterised by low number of platelets, affecting approximately 60,000 adults in the United States.

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.

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 1,400 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 www.sobi.com.

For more information please contact

Paula Treutiger, Head of Communication & Investor Relations
+46 733 666 599
paula.treutiger@sobi.com

Linda Holmström, Corporate Communications & Investor Relations
+46 708 734 095
linda.holmstrom@sobi.com