PRESS RELEASE

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Sobi presents comprehensive study data on extended half-life haemophilia treatments at EAHAD

Sobi™ will present data at the European Association of Haemophilia and Allied Disorders (EAHAD) conference in Prague, Czech Republic, 6-8 February 2019, showing evidence on the safety, efficacy and long-term benefits of its extended half-life products for the treatment of haemophilia. The studies that will be presented support Sobi's commitment to develop a treatment paradigm that expand the possibilities and transform life for people with haemophilia.

Sobi and our collaboration partner Sanofi will provide interim data on the incidence of inhibitors in previously untreated patients (PUPs) with severe haemophilia A treated with factor VIII Fc fusion protein (Elocta®): the PUPs A-LONG study. PUPs A-LONG is an open-label, single-arm, multicentre, phase 3 study of rFVIIIFc prophylaxis in PUPs with severe haemophilia A. This interim analysis will be the first data reported on PUPs for an extended half-life product. As the study is still ongoing, the final results will be presented at a future conference.

The long-term safety and efficacy of prophylactic treatment with recombinant factor VIII Fc fusion protein and factor IX Fc fusion protein (Alprolix®) in adults, adolescents and children, with haemophilia A and B respectively, will also be presented in longitudinal analyses of the final data from Sobi and Sanofi's study programme A-LONG/Kids A-LONG/ASPIRE and B-LONG/Kids B-LONG/B-YOND.

"We are proud to present such comprehensive data on rFVIIIFc and rFIXFc. The ASPIRE and B-YOND studies, being the longest studies carried out on extended half-life therapies for haemophilia A and B respectively, show the possibilities that these therapies can offer patients," says Milan Zdravkovic, Head of R&D and Chief Medical Officer 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:

- Incidence of inhibitors in previously untreated patients with severe haemophilia A treated with rFVIIIFc: the PUPs A-LONG study: Hot topics session, Friday 8 Feb 2019, 13:15 – 14:15. Oral presentation #OR14
- Long-term efficacy and safety of prophylactic treatment with recombinant factor IX Fc fusion protein (rFIXFc) in subjects with severe or moderate haemophilia B: final longitudinal analysis of B-LONG/Kids B-LONG and B-YOND: Poster #P009

- Long-term efficacy and safety of prophylactic treatment with recombinant factor VIII Fc fusion protein (rFVIIIFc) in subjects with severe haemophilia A: final longitudinal analysis of A-LONG/Kids A-LONG and ASPIRE: Poster #P039
- Improvements in joint health during long-term use of recombinant factor VIII Fc fusion protein prophylaxis in subjects with haemophilia A: Poster #P158
- Improvement in target joint bleeding during long-term use of recombinant factor IX Fc fusion protein prophylaxis in subjects with haemophilia B: Poster #P167
- Update on the verITI-8 study: a global, multicentre, open-label, interventional study evaluating recombinant factor VIII Fc fusion protein for first-time immune tolerance induction (ITI) therapy: Poster #P179
- Assessment of clotting activity of recombinant FIXFc fusion protein in French Haemostasis laboratories: Poster #P059
- A simple functional mobility assessment tool for use in clinical practice or real-life studies with haemophilia patients: step 1, development of the questionnaire (French): Poster #P068

All oral and poster presentations can be accessed via the official EAHAD 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, 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 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, as well as 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.[i]
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.[ii] The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.[iii]

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 rFVIIIFc-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.

For more information please contact

Media relations Sobi
Linda Holmström, Senior Communications Manager
+46 70 873 40 95
linda.holmstrom@sobi.com

Investor relations Sobi
Jörgen Winroth, Vice President, Head of Investor Relations
+1 347 224 0819, +1 212 579 0506
jorgen.winroth@sobi.com

[i] The WFH Annual Global Survey 2017 https://www.wfh.org/en/data-collection
[ii] 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.
[iii] 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.