PRESS RELEASE

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Long-term safety and efficacy extension study data of Alprolix® for haemophilia B published in *Thrombosis and Haemostasis*

- Median prophylactic dosing interval of 13.7 days in 86% of adult/adolescent subjects in individualized Alprolix treatment group

- Long-term safety and low annual bleed rate maintained in longest study of an extended half-life therapy for haemophilia B

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO: SOBI) and Bioverativ Inc. (NASDAQ: BIVVV) today announce that interim results from the B-YOND extension trial, which studies Alprolix® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] in previously treated subjects with severe haemophilia B, were published in the March 2017 issue of Thrombosis and Haemostasis. The study results reinforce the long-term safety and efficacy of prophylactic treatment with Alprolix over a median duration of more than three years in adults/adolescents and more than a year and a half in children under 12 years of age. The primary outcome measure was development of inhibitors (neutralizing antibodies that can interfere with activity of the therapy); no patients treated with Alprolix in the study developed inhibitors.

“The interim data from B-YOND confirm the safety profile of Alprolix, and show that adult, adolescent and paediatric subjects maintained low annual bleed rates with prophylactic dosing of Alprolix every 1-2 weeks,” said John Pasi, MD, PhD, principal investigator of the study, Professor of Haemostasis and Thrombosis at The Royal London Hospital, Barts and the London School of Medicine and Dentistry. “These results come from the longest-term study of an extended half-life therapy for haemophilia B and provide physicians across the globe with important insights and information about the treatment of haemophilia B.”

B-YOND is an ongoing open-label, nonrandomized extension study, and eligible previously-treated patients who completed B-LONG or Kids B-LONG could enrol in one of three treatment groups: weekly prophylaxis, individualized prophylaxis, and modified prophylaxis. An episodic treatment arm is also available only to adult and adolescent participants. At the time of the interim data cut, 116 male subjects (93 from B-LONG and 23 from Kids B-LONG) were enrolled in the study.

“These results confirm the long-term safety and efficacy profile of Alprolix and show that a majority of the participants in the study were able to dose once weekly or less frequently while maintaining adequate protection,” said Maha Radhakrishnan, MD, senior vice president of medical at Bioverativ.

In the individualized prophylaxis treatment group, as of the B-YOND interim data cut, a total of 26 adolescent/adult subjects out of 30 (86.7%) had a dosing interval longer than one week with a median dosing interval of 13.7 days, and paediatric subjects aged 6 to <12 years had a median dosing interval of 10.0 days. Fifteen of 26 (57.7%) adult/adolescent subjects in the individualized prophylaxis treatment group had a dosing interval of every 14 days or longer.

“Together with Bioverativ, we remain focused on advancing research to better understand the underlying science and potential benefits of Alprolix for people with haemophilia B,” said Krassimir Mitchev, MD, PhD, vice president and medical therapeutic area head of Haemophilia at Sobi.

Growing body of evidence further reinforces the safety and efficacy of Alprolix

The overall median annualized bleeding rate (ABR) at the time of the B-YOND interim data cut was 2.3 for adult/adolescent participants in both the weekly and individualized prophylaxis treatment groups, and 2.4 for those in the modified prophylaxis study arm. Participants receiving on-demand therapy, or treatment when a bleeding episode occurred, had a median ABR of 11.3.

Among children under age six (n=9), the median ABR in the weekly prophylaxis group was zero. For children between six and 12 years old, the median ABR was similar in the weekly (2.7; n=10) and individualized (2.4; n=5) prophylaxis groups. The one participant from the 6 to <12 years cohort who was in the modified prophylaxis group had an ABR of 3.1.

In the B-YOND study as of the interim data cut, Alprolix was well tolerated and adverse events (AEs) were typical of the haemophilia B populations studied. The most common AEs were headache (n=14, 12.1%) and common cold (n=13, 11.2%), and the majority of AEs were considered by the investigator to be unrelated to ALPROLIX treatment. A total of 39 serious AEs (SAEs) were reported in 23 participants (19.8%) treated with ALPROLIX. All SAEs were assessed by the investigator as unrelated to Alprolix, with the exception of one SAE of renal colic in an adult/adolescent participant with a medical history of previous clot colic; the event resolved and did not lead to study discontinuation. In the study as of the interim data cut, there were no reports of serious allergic reactions or anaphylaxis associated with Alprolix, no vascular thrombotic events, and no deaths.

The full publication is available online at https://th.schattauer.de

About the B-YOND study
B-YOND enrolled 116 previously-treated males, including 93 participants (81%) who completed B-LONG, and 23 (100%) of those who completed Kids B-LONG. The primary outcome measure is development of inhibitors. Secondary endpoints include the annualized number of bleeding episodes per subject (including spontaneous joint bleeding rates), Alprolix exposure days per participant, Alprolix consumption (total IU/kg per subject per year), and the participant's assessment of response to treatment of a bleeding episode.

From the start of B-LONG to the B-YOND interim data cut, adult/adolescent subjects had a median of 39.5 months of cumulative Alprolix treatment, and a median of 162 cumulative Alprolix exposure days. From the start of Kids B-LONG to the B-YOND interim data cut, paediatric subjects had a median of 21.9 months of cumulative Alprolix treatment, and a median of 94 cumulative Alprolix exposure days.

About Alprolix®
Alprolix® (eftrenonacog alfa) [Coagulation Factor IX (Recombinant), Fc Fusion Protein], 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). While Fc fusion technology has been used for more than 15 years, Bioverativ and Sobi have optimized the technology and are the first companies to utilize it in the treatment of haemophilia. Alprolix is manufactured using a human cell line in an environment free of animal and human additives.

Alprolix is approved and marketed by Bioverativ for the treatment of haemophilia B in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, and Bioverativ has marketing rights in these regions. It is also authorised in the European Union, Iceland, Liechtenstein, Norway and Switzerland, where it is marketed by Sobi.

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 B
Haemophilia B is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting.[i] The World Federation of Hemophilia estimates that approximately 28,000 people are currently diagnosed with haemophilia B worldwide.[ii]

People with haemophilia B may experience bleeding episodes in joints and muscles that cause pain, decreased mobility and irreversible joint damage. In the worst cases, these bleeding episodes can cause organ bleeds and life-threatening haemorrhages. Injections of factor IX temporarily replace clotting factors necessary to resolve bleeding and, when used prophylactically, to prevent new bleeding episodes.[i]

About the Bioverativ and Sobi™ collaboration
Bioverativ and Sobi collaborate on the development and commercialisation of Alprolix and ELOCTATE/Elocta. Bioverativ 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 ELOCTATE and Alprolix. Sobi has final development and commercialization rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets).

About Bioverativ
Bioverativ (NASDAQ: BIVV) is a global biotechnology company dedicated to transforming the lives of people with hemophilia and other rare blood disorders through world-class research, development and commercialization of innovative therapies. Launched in 2017 following separation from Biogen Inc., Bioverativ builds upon a strong heritage of scientific innovation and is committed to actively working with the blood disorders community. The company's mission is to create progress for patients where they need it most and its hemophilia therapies when launched represented the first major advancements in hemophilia treatment in more than two decades. For more information, visit www.bioverativ.com or follow @bioverativ on Twitter.

Bioverativ was created as a spin-off from Biogen's hemophilia business and separated from Biogen effective February 1, 2017. Bioverativ is an independent, publicly-traded company, headquartered in Waltham, Massachusetts, USA. During a temporary, transition period, which includes time to allow Bioverativ to establish certain licenses and consents related to ELOCTATE® and ALPROLIX, each of Bioverativ and Biogen will have a relationship to the products.

About Sobi™
Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2015, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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[i] World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: http://www.wfh.org/en/page.aspx?pid=637#Difference_A_B. Accessed on: January, 13, 2017.
[ii] World Federation of Hemophilia. Report on the Annual Global Survey 2013. Available at: http://www1.wfh.org/publications/files/pdf-1591.pdf. Accessed on: January 13, 2017.