PRESS RELEASE

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Long-term safety and efficacy data of extended half-life therapy Alprolix® in children with haemophilia B published in *The Lancet Haematology*

- *Pediatric findings align with adult/adolescent study results of Alprolix*

Swedish Orphan Biovitrum AB (publ) (Sobi™) and Bioverativ Inc. (NASDAQ: BIVVV) today announce that results from the Kids B-LONG Phase 3 clinical trial, which studied Alprolix® [eftrenonacog alfa, Coagulation Factor IX (Recombinant), Fc Fusion Protein] in previously-treated children with severe haemophilia B, were published in *The Lancet Haematology*. The primary outcome measure of the trial was development of inhibitors, and no patients treated with Alprolix in the study developed inhibitors. Treatment was generally well tolerated and resulted in low bleeding rates in participants, most of whom remained on once-weekly dosing during the study. The manuscript, entitled "*Recombinant Factor IX Fc Fusion Protein in Children with Haemophilia B (Kids B-LONG): Results from a Multicentre, Non-Randomised Phase 3 Study*," was published in the February 2017 issue of *The Lancet Haematology*.

"The Medical and Scientific Advisory Council of the National Hemophilia Foundation recommends that prophylaxis be considered the optimal treatment regimen for people with severe haemophilia B, and be initiated early based on the body of evidence demonstrating improved long-term clinical outcomes," said Roshni Kulkarni, MD, Department of Paediatrics and Human Development, Michigan State University, East Lansing, Michigan, United States, and investigator in the study. "To date, Kids B-LONG is the largest study to evaluate the safety and efficacy of extended half-life factor IX therapy in children with haemophilia B, and the study's results align with those in studies of Alprolix in adults and adolescents."

Kids B-LONG investigated the safety, efficacy and pharmacokinetics (measurement of the presence of the drug in a person's body over time) of Alprolix in previously treated children under the age of 12 with severe haemophilia B (n=30). The primary outcome measure was development of inhibitors (neutralizing antibodies that can interfere with the activity of the therapy). Secondary outcomes included pharmacokinetics, annualized bleeding rate (ABR), and the number of injections required to resolve a bleed.

In this study, no participants developed inhibitors to Alprolix. Alprolix was well tolerated and adverse events (AEs) observed were typical of the paediatric haemophilia B population. The most common AEs were common cold (n=7, 23%) and fall (n=6, 20%). Four participants experienced serious AEs during the study, all of which were assessed as unrelated to Alprolix by the investigators. In the study, there were no reports of anaphylaxis or serious hypersensitivity reactions to Alprolix, no vascular thrombotic events, and no deaths.

Children (n=30) treated prophylactically with Alprolix had a median ABR of 2.0 overall and zero spontaneous joint bleeds. Of all patients treated, 10 of 30 (33%) experienced no bleeding episodes, and 19 of 30 (63%)

reported no joint bleeding on-study. Overall, 92 per cent of bleeding episodes were controlled by one or two injections of Alprolix. Following a switch to Alprolix therapy, 80 per cent of children extended their dosing interval compared to previous treatment, and nearly all remained on once-weekly prophylactic dosing throughout the study.

“These data in children reaffirm the well-characterized efficacy and safety profile of Alprolix as demonstrated in studies of adults and adolescents with haemophilia B, and they build on the robust real-world experience of Alprolix over more than two years,” said Maha Radhakrishnan, MD, senior vice president of medical at Bioverativ. “Together with Sobi, we are committed to advancing the care of people with haemophilia around the world.”

“Through Fc fusion technology, Alprolix uses the body’s natural pathway to prolong the time the therapy remains in the body,” said Krassimir Mitchev, MD, PhD, vice president and medical therapeutic area head of haemophilia at Sobi. “Along with Bioverativ, we are dedicated to furthering the study of real-world clinical use of Alprolix and continuing to explore the potential of Fc fusion technology to address the significant unmet needs that remain in haemophilia.”

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About B-LONG
Kids B-LONG was a global, open-label, multicentre Phase 3 study involving 30 boys under the age of 12 with severe haemophilia B (factor IX activity equal to or less than 2 IU per dL, or 2%) with at least 50 prior exposure days to factor IX therapies. To date, Kids B-LONG is the largest study to evaluate extended half-life factor IX therapy in children with haemophilia B. The study was conducted at 16 haemophilia treatment centres in Australia, Hong Kong, Ireland, the Netherlands, South Africa, the UK, and the United States. Overall, 27 participants (90%) completed the study. The median time participants spent in the study was 49.4 weeks, and 24 participants received Alprolix injections on at least 50 separate days (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 optimised the technology and are the first companies to utilise 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 for the treatment of haemophilia B the European Union, Iceland, Liechtenstein, Norway and Switzerland, and marketed by Sobi. It is also approved in the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries, and Bioverativ has marketing rights in these regions.

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 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 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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).

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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.