PRESS RELEASE

Stockholm, Sweden, 11 December 2017

New data show extended prophylactic dosing with Alprolix® provides safe and effective protection in people with severe haemophilia B

Post-hoc longitudinal analysis from B-LONG and B-YOND studies shows patients who progressed to individualised prophylactic dosing intervals of 14 days or longer maintained low annualised bleeding rates.

Swedish Orphan Biovitrum AB (publ) (Sobi™)(STO:SOBI) and Bioverativ Inc. (NASDAQ: BIVVV) today announce the results of a new post-hoc longitudinal analysis demonstrating that individualised dosing with extended half-life therapy, Alprolix® (eftrenonacog alfa), every 14 or more days may be a potential option for people with severe haemophilia B who seek the benefits of protection from a prophylactic therapy with reduced treatment burden. The analysis is being presented in a poster session at the 59th Annual Meeting of the American Society of Hematology (ASH).

Alprolix is a recombinant clotting factor IX therapy developed using Fc fusion technology to prolong circulation in the body. Alprolix has the longest real-world experience of any haemophilia B extended half-life therapy and been studied in more than 150 adult, adolescent, and paediatric patients over three years as part of a robust clinical development programme and an extension study.

Using data from the pivotal Phase 3 B-LONG study in 123 patients with severe haemophilia B, and B-YOND, the long-term extension study of Alprolix that included 93 patients from B-LONG, researchers evaluated long-term outcomes of 22 study participants (adults and adolescents ≥12years) in the individualised treatment group who progressed to long-term prophylactic dosing regimens of 14 days or longer. Data from this longitudinal analysis showed these study participants achieved consistent bleed protection with extended prophylactic dosing intervals for up to three years.

“These data show that individualised prophylactic treatment with Alprolix, starting at weekly or ten day dosing intervals with the possibility to extend to 14 days or longer, has the potential to deliver optimal protection against bleeds for people with haemophilia B,” said Maha Radhakrishnan, M.D., Senior Vice President of Medical at Bioverativ. “Individualised dosing intervals allow patients and their physicians to personalise treatment plans that balance the need to maximize bleed protection while minimizing treatment burden. We remain committed to improving the long-term outcomes for people with haemophilia B.”

Data for 22 study participants on varying pre-study treatment regimens, including those who switched to extended dosing at any time during the study, were included in this longitudinal review. Prior to treatment with Alprolix, 10 of the 22 study participants had received prophylactic treatment and 12 participants were on episodic treatment. Results from this analysis showed that:

- Patients who received pre-study prophylactic treatment were well protected with extended dosing intervals of 14 days or longer with an annualised bleed rate (ABR) of 1.8 as compared to 2.0 pre-study.
- Median ABR decreased from 25 (22-36) to 1.4 (0.6-5.8) for the participants who received pre-study episodic treatment
- The median (IQR) duration of treatment on the ≥14-day regimen in the 22 patients was 3.4 (1.8-4.0) years
- Study participants treated with ≥14 dosing intervals were well controlled with a median spontaneous ABR of 0.7 over 3 years

"These findings reinforce a history of successfully delivering long-acting protection against spontaneous and joint bleeds in haemophilia B by dosing with Alprolix at one to two-week intervals," said Armin Reininger, M.D.,Ph.D., Head of Medical and Scientific Affairs, Sobi. "In collaboration with Bioverativ, we will continue to explore the potential of Alprolix to reduce the burden of disease and create meaningful improvement in the lives of people living with haemophilia."

Earlier at ASH, Bioverativ presented data from the preclinical imaging study, Extravascular Distribution of Conventional and EHL FIX Products Using In Vivo SPECT Imaging Analysis in Haemophilia B Mice, which showed that Alprolix demonstrates higher tissue distribution and retention in joint areas compared to other factor IX molecules. These results were part of an ongoing imaging collaboration with Invicro, LLC, to investigate the impact of extravascular distribution of factor IX therapies, including Alprolix, on protection from bleeds and improvement in joint health.

About the B-YOND extension 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.

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 29,700 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 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). 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, Switzerland, Kuwait and Saudi Arabia 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 Bioverativ

Bioverativ is a global biopharmaceutical 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.

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 2016, 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.

About the Bioverativ and Sobi collaboration

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

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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, Annual Global Survey 2016, published in October 2017. Available at: http://www.wfh.org/en/data-collection