Biogen and Sobi Announce European Medicines Agency Validates ALPROLIX® (rFIXFc) Marketing Authorization Application

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CAMBRIDGE, Mass. & STOCKHOLM--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) and Swedish Orphan Biovitrum AB (publ) (Sobi) (STO: SOBI) today announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) of ALPROLIX® (rFIXFc), a recombinant factor IX Fc fusion protein product candidate for the treatment of hemophilia B. This validation signifies the initiation of the EMA's review process.

The MAA includes results from two global, Phase 3 clinical trials examining the efficacy, safety and pharmacokinetics (a measure of the presence of the therapy in a person's body over time) of ALPROLIX for hemophilia B: the pivotal B-LONG study for previously treated adults and adolescents, and Kids B-LONG study for previously treated children under age 12.

ALPROLIX is a recombinant, clotting factor IX therapy and is currently approved for the treatment of hemophilia B in the U.S., Canada, Japan and Australia. It is the only approved hemophilia B therapy to demonstrate prolonged clotting factor circulation in the body.

"The acceptance of this MAA is an important milestone in our goal to bring this innovative therapy to the European hemophilia community," said Douglas E. Williams, Ph.D., executive vice president of Research and Development at Biogen. "We look forward to working with European regulators to help people with hemophilia B in Europe realize the benefits that treatment with ALPROLIX may offer."

Biogen and Sobi are collaborators in the development and commercialization of ALPROLIX for hemophilia B. Sobi has an opt-in right to assume final development and commercialization of ALPROLIX for the Sobi territories (essentially, Europe, North Africa, Russia and certain Middle Eastern markets). Biogen leads development for ALPROLIX, has manufacturing rights, and has commercialization rights in North America and all other regions in the world excluding the Sobi territories.

"Our collaboration with Biogen remains focused on the goal of transforming the care of people living with hemophilia," said Birgitte Volck, M.D., Ph.D., senior vice president of Development and chief medical officer of Sobi. "The validation of the ALPROLIX MAA marks a critical regulatory milestone in our continued, collaborative global efforts."

About Hemophilia B

The World Federation of Hemophilia global survey conducted in 2013 estimates that approximately 28,430 people are currently diagnosed with hemophilia B worldwide. It is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting. People with hemophilia B experience bleeding episodes that cause pain, irreversible joint damage, and life-threatening hemorrhages. Prophylactic infusions of factor IX temporarily replace clotting factors necessary to control bleeding and prevent new bleeding episodes.

About the B-LONG Clinical Study

B-LONG was a global, open-label, multi-center Phase 3 study that evaluated the efficacy, safety and pharmacokinetics of ALPROLIX in 123 males aged 12 years and older with severe hemophilia B and a history of at least 100 exposure days on any currently available factor IX therapy. The study involved 50 hemophilia treatment centers in 17 countries on six continents. It examined the effect of ALPROLIX for prophylaxis, episodic (on-demand) treatment, and during surgery (perioperative management). Starting prophylaxis regimens were either 50 IU/kg once weekly or 100 IU/kg every 10 days. The dose or interval could be adjusted as clinically indicated.

About the Kids B-LONG Clinical Study

Kids B-LONG was a global, open-label, multicenter Phase 3 study involving 30 boys under age 12 with severe hemophilia B and at least 50 prior exposure days to factor IX therapies.

Participants in both the B-LONG and Kids B-LONG clinical trials were able to enroll in BYOND, a long-term extension clinical study evaluating the safety and efficacy of ALPROLIX, which is currently ongoing.

For more information about these studies, please visit www.biogen.com.

About ALPROLIX

ALPROLIX is a recombinant, clotting factor therapy developed for hemophilia B by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG_1 (a protein commonly found in the body). It is believed that this enables ALPROLIX to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion has been used for more than 15 years, Biogen is the only company to apply it in hemophilia.

Common adverse reactions (incidence of greater than or equal to 1 percent) from the B-LONG study were headache and oral paresthesia (an abnormal sensation in the mouth).

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For product labeling, press releases and additional information about the Company, please visit www.biogen.com.

About Sobi

Sobi is an international specialty healthcare company dedicated to rare diseases. Our 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. We also market a portfolio of specialty and rare disease products for partner companies across Europe, the Middle East, North Africa and Russia. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the potential and therapeutic impact of ALPROLIX. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “project,” “target,” “will” and other words and terms of similar meaning. You should not place undue reliance on these statements. Drug development and commercialization is a lengthy and complex process and involve a high degree of risk. Factors which could cause actual results to differ materially from our current expectations include the risk that unexpected concerns may arise from additional data or analysis, European regulatory authorities may require additional information or further studies, or may fail to approve, or refuse to approve, or may delay approval of our marketing authorization application for ALPROLIX, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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