Biogen Idec and Sobi Announce European Medicines Agency Validates ELOCTA™ (rFVIIIFc) Marketing Authorization Application for Review

October 31, 2014

CAMBRIDGE, Mass. & STOCKHOLM--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Swedish Orphan Biovitrum AB (publ) (Sobi) (STO: SOBI) today announced that the European Medicines Agency (EMA) has validated the Marketing Authorization Application (MAA) of ELOCTA ™ (rFVIIIFc), a recombinant factor VIII Fc fusion protein product candidate for the treatment of hemophilia A. The validation of the MAA initiates the EMA's review process.

ELOCTA is the European trade name for rFVIIIFc, which is also known as ELOCTATE ™ [Antihemophilic Factor (Recombinant), Fc Fusion Protein] in the U.S., Canada, and Australia, where it is approved for the treatment of hemophilia A. ELOCTATE is the first recombinant clotting factor VIII therapy with prolonged circulation to provide protection from bleeding episodes with the potential for an extended interval between prophylactic injections.

"The validation of ELOCTA's application by the EMA is an important step toward bringing this innovative treatment to people with hemophilia A in Europe," said Douglas E. Williams, Ph.D., executive vice president of Research and Development at Biogen Idec. "ELOCTA has the potential to protect against bleeding episodes while helping to address the challenge of frequent injections."

The regulatory application included results from the pivotal, Phase 3 clinical study, A-LONG that examined the efficacy, safety and pharmacokinetics of rFVIIIFc in males 12 years of age and older with severe hemophilia A and from the Phase 3 clinical study, Kids A-LONG that evaluated the efficacy and safety of rFVIIIFc in children with hemophilia A under 12 years of age.

Biogen Idec and Sobi are collaborators in the development and commercialization of ELOCTATE/ELOCTA for hemophilia A. Sobi has an opt-in right to take over final development and commercialization of ELOCTA for the Sobi territories (Europe, North Africa, Russia and most Middle Eastern markets). Biogen Idec leads development for ELOCTATE/ELOCTA, has manufacturing rights, and has commercialization rights in North America and all other regions in the world excluding the Sobi territories.

"Sobi and Biogen Idec are committed to addressing significant medical needs in the global hemophilia community," said Birgitte Volck, M.D., Ph.D., senior vice president development and chief medical officer of Sobi. "We're working collaboratively to deliver innovative medicines that have the potential to change the way hemophilia A is treated."

About Hemophilia A

Hemophilia A is a rare, chronic, genetic disorder in which the ability of a person's blood to clot is impaired, due to missing or reduced levels of a protein known as factor VIII. People with hemophilia A experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening hemorrhages. The World Federation of Hemophilia global survey conducted in 2012 estimates that approximately 142,000 people worldwide are identified as living with hemophilia A.

About the A-LONG Clinical Study

The Phase 3 A-LONG clinical study was an open-label, multi-center study involving 165 previously treated males 12 years of age and older with severe hemophilia A. The study evaluated individualized and weekly prophylaxis to reduce or prevent bleeding episodes, and on-demand dosing to treat bleeding episodes. In the individualized arm, each study participant started on a twice-weekly dosing regimen. Participants' pharmacokinetic parameters were used to guide adjustments to dosing interval (every three to five days), and dose (25 to 65 IU/kg) to target a minimum factor VIII level of 1 to 3 IU/dL or higher as needed to prevent and control breakthrough bleeding episodes. In the study, the dose in the weekly prophylaxis arm was 65 IU/ kg/week.

About the Kids A-LONG Clinical Study

The Kids A-LONG study is the first clinical study to evaluate an investigational hemophilia therapy with a prolonged half-life in children younger than 12 years of age. The study was a global, open-label, multi-center Phase 3 study involving 71 boys with severe hemophilia A with at least 50 prior exposure days to factor VIII therapies.

Participants in both the A-LONG and Kids A-LONG clinical trials were able to enroll in ASPIRE, a long-term extension clinical study evaluating the safety and efficacy of ELOCTATE. For more information about these studies, please visit www.biogenidec.com.

About ELOCTA

ELOCTA is an investigational, recombinant clotting factor therapy developed for hemophilia A by fusing factor VIII 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 ELOCTA to use a naturally occurring pathway to prolong the time therapy remains in the body. While Fc fusion has been used for more than 15 years, Biogen Idec is the only company to apply it to the treatment of hemophilia.

About Biogen Idec

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company 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.biogenidec.com.

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 Inflammation and Genetic diseases, with two late stage biological development projects within Haemophilia. Sobi also markets a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2013, Sobi had total revenues of SEK 2.2 billion (€253 M) and about 550 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

Biogen Idec Safe Harbor

This press release contains forward-looking statements, including statements about the potential therapeutic impact of ELOCTA. 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 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 may delay approval of our marketing authorization application for ELOCTA, 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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