Biogen and Sobi to Showcase Long-Term Efficacy and Safety Data from Extended Half-Life Hemophilia Therapies at World Federation of Hemophilia 2016 World Congress

July 18, 2016

Longitudinal Joint Health Data from Patients in the A-LONG, ASPIRE, B-LONG and B-YOND Trials to be Presented

CAMBRIDGE, Mass. & STOCKHOLM--(BUSINESS WIRE)--Biogen (NASDAQ:BIIB) and Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) will present updated data on long-term safety and efficacy of the companies' novel extended half-life therapies, ELOCTATE ® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] (marketed as ELOCTA® in Europe) for hemophilia A and ALPROLIX® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] for hemophilia B. The data from the Phase 3 extension studies, B-YOND (hemophilia B) and ASPIRE (hemophilia A), will be highlighted in oral and poster presentations at the World Federation of Hemophilia (WFH) 2016 World Congress in Orlando, Florida, from July 24–28, 2016.

"The breadth of research, for both marketed products and preclinical programs being presented at WFH reflects our commitment to hemophilia and our mission to improve the lives of people living with hemophilia." said Rob Peters, vice president, rare disease research at Biogen.

For people with severe hemophilia A and B, most bleeding events occur in joints, with joint damage being the most common complication of the condition.[1]

Post hoc analyses to be presented at the WFH Congress include longitudinal evaluation of joint health from patients participating in A-LONG and ASPIRE and target joint data from a subset of patients participating in B-LONG and B-YOND.

Additionally, preclinical pharmacokinetic data from intravenous and subcutaneous administration of recombinant FVIIIFc-VWF-XTEN, a fusion protein being investigated for the treatment of hemophilia A, that utilizes XTEN™ technology licensed from Amunix, will be presented.

"ELOCTATE and ALPROLIX are backed by robust clinical data and significant real-world experience. We believe these new data presentations will help healthcare providers to deepen their understanding of the clinical value and utility of these innovative medicines," said Krassimir Mitchev, M.D., Ph.D., vice president and medical therapeutic area head of Haemophilia at Sobi.

ELOCTATE and ALPROLIX are the first approved hemophilia A and B Fc fusion therapies to provide extended protection against bleeding episodes. They utilize Fc fusion technology, which uses a naturally occurring pathway to prolong the time the therapy remains in the body.

Select presentations include:

ELOCTATE/ALPROLIX-Focused Presentations:

- Longitudinal Modified Hemophilia Joint Health Scores (mHJHS) Outcomes With Recombinant Factor VIII Fc Fusion Protein (rFVIIIFc) Prophylaxis in Subjects With Severe Hemophilia A – Oral Presentation # T-02 – Tuesday, July 26, 2:55 – 3:05 ET
- Longitudinal Analysis of Annualized Bleeding Rates Among Adults/Adolescents Receiving Weekly Prophylaxis With rFVIIIFc in A-LONG and ASPIRE – Poster # P150 – Monday, July 25, 10:00 – 10:45 & 3:45 – 4:30 ET
- Post Hoc Analysis to Evaluate the Effect of Recombinant Factor IX Fc Fusion Protein (rFIXFc) Prophylaxis in Adults and Adolescents with Target Joints and Hemophilia B – Poster # P83 – Tuesday, July 26, 10:00 – 10:45 ET

Preclinical rFVIIIFc-VWF-XTEN Presentation:

- The pharmacokinetic profiles of intravenously and subcutaneously administered recombinant FVIIIFc-VWF-XTEN in cynomolgus monkey – Oral Presentation W-01 – Wednesday, July 27, 10:45 – 11:00 ET

Biogen recently announced that it intends to spin off its hemophilia business as an independent, publicly-traded company. The new company will focus on meaningfully improving the treatment and care of people living with hemophilia, with existing marketed products to include ELOCTATE and ALPROLIX, indicated for the treatment of hemophilia A and B, respectively. The new company will continue to collaborate with Sobi once it is independent.

About Hemophilia A and B

Hemophilia is a rare, genetic disorder in which the ability of a person's blood to clot is impaired. Hemophilia A occurs in about one in 5,000 male births annually, and more rarely in females, affecting about 16,000 people in the United States. Hemophilia B occurs in about one in 25,000 male births annually, and more rarely in females, affecting about 4,000 people in the United States. Worldwide, it is estimated that more than 400,000 people are living with hemophilia.

People with hemophilia A or B experience prolonged bleeding episodes that can cause pain, irreversible joint damage and life-threatening hemorrhages. Prophylactic infusions of factor VIII or IX can temporarily replace the missing clotting factors that are needed to control bleeding and prevent new bleeding episodes.[2] The Medical and Scientific Advisory Council of the National Hemophilia Foundation recommends prophylaxis as the optimal therapy for people with severe hemophilia A or B.[3]

About ELOCTATE®/ELOCTA®

ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein], the first recombinant clotting factor VIII therapy with prolonged circulation in the body, is approved in the United States, Canada, Australia, New Zealand and Japan, as well as the European Union, Switzerland, Iceland, Liechtenstein and Norway (as ELOCTA®). It was developed for hemophilia A by fusing factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables ELOCTATE to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Sobi and Biogen are the first companies to utilize it in the treatment of hemophilia.

Inhibitors have been reported with factor replacement therapy in the treatment of hemophilia A. Inhibitor development has been observed with rFVIIIFc (ELOCTATE/Elocta) in the treatment of hemophilia A, including previously untreated patients.

About ALPROLIX®

ALPROLIX® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] (rFIXFc) is a recombinant clotting factor therapy developed for hemophilia B by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables ALPROLIX to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Sobi and Biogen are the first companies to utilize it in the treatment of hemophilia.

ALPROLIX is currently approved for the treatment of hemophilia B in the U.S., Canada, Japan, Australia, New Zealand, and most recently, the European Union as well as Iceland, Liechtenstein and Norway (as Alprolix®). As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur following administration of ALPROLIX.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. 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 more information, please visit www.biogen.com. Follow us 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 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 Biogen and Sobi Collaboration

Biogen and Sobi collaborate on the development and commercialization of ELOCTATE and ALPROLIX. Sobi has final development and commercialization rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Biogen has manufacturing responsibility for ELOCTATE and ALPROLIX and has final development and commercialization rights in North America and all other regions in the world excluding the Sobi territory.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the potential benefits and efficacy of ELOCTATE® in hemophilia A and ALPROLIX® in hemophilia B, and the proposed spin-off of Biogen's hemophilia business. 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. These statements involve risks and uncertainties that could cause Biogen's actual results to differ materially from those reflected in such statements, including, without limitation, unexpected concerns that may arise from additional data or analysis, regulatory authorities may require additional information or further studies, regulatory authorities may fail to approve or may delay approval of Biogen's drug candidates or expansion of product labeling, and risks and uncertainties relating to the completion and anticipated benefits of the proposed spin-off of Biogen's hemophilia business. For more detailed information on the risks and uncertainties associated with Biogen's drug development and commercialization activities and the proposed spin-off of Biogen's hemophilia business, please review the Risk Factors section of Biogen's most recent annual or quarterly report filed with the Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this press release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

[1] Hemophilia Federation of America. Joint Damage. Available at: http://www.hemophiliafed.org/bleeding-disorders/complications/joint-damage/. Accessed on July 6, 2016.

[2] 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: June 17, 2016.

[3] National Hemophilia Foundation. MASAC Recommendation Concerning Prophylaxis. Available at: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendation-Concerning-Prophylaxis. Accessed on June 17, 2016.

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