Data Reinforcing the Long-Term Safety and Efficacy of Extended Half-Life Hemophilia Therapies ELOCTATE® and ALPROLIX® Highlighted at 58th ASH Meeting

December 3, 2016

New Longitudinal Data Show Long-Term Prophylactic Use of ELOCTATE Resulted in Effective Target Joint Resolution and Improved Quality of Life Measures

SAN DIEGO--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) and Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) will present new data, including updated longitudinal safety and efficacy findings from phase 3 and extension studies, on the companies' extended half-life therapies, ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] (marketed as Elocta® in Europe and the Middle East) for hemophilia A and ALPROLIX® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] for hemophilia B, at the 58th American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego, California, from December 3-6.

The presentations include efficacy data, which show low target joint annual bleeding rates and effective target joint resolution (≤2 spontaneous bleeding episodes over one year) in pediatric, adolescent and adult patients on long-term prophylaxis with ELOCTATE. Target joints occur when people with hemophilia experience frequent bleeds in the same joint, and can lead to chronic joint disease. An 18% improvement in hemophilia-related quality of life measures (Haem-A-QOL) was seen in adolescents and adults who experienced target joint resolution with prophylactic treatment with ELOCTATE as compared to baseline measurements at phase 3 study entry, with the most impact (≥ 20%) in areas such as physical health, sports and leisure, and work and school.

Biogen will also present preclinical data on recombinant FIXFc-XTEN, a fusion protein being investigated for once-weekly, subcutaneous treatment of hemophilia B. The rFIXFc-XTEN program is currently being developed solely by Biogen and utilizes XTEN® technology licensed from Amunix. Depending on Biogen's development activities and other factors, it is subject to an opt-in right by Sobi in the future.

"The data presented at ASH, coupled with the real-world experience of ELOCTATE and ALPROLIX, may help patients, clinicians and policymakers better understand the long-term safety and sustained efficacy profile for these therapies," said Maha Radhakrishnan, MD, vice president, medical, at Biogen and head of medical at Bioverativ Inc., a spin-off of Biogen's hemophilia business that is on track to launch in early 2017. "We also remain deeply committed to developing new treatments that can make a meaningful impact in the lives of people with hemophilia."

"We are encouraged to see data that show ELOCTATE can improve the quality of life for people with hemophilia A," said Krassimir Mitchev, MD, PhD, vice president and medical therapeutic area head of Haemophilia at Sobi. "Sobi, together with Biogen, is strongly committed to ensuring sustainable access to ELOCTATE/Elocta for people living with hemophilia A across our respective markets."

ELOCTATE and ALPROLIX have more than two years of real-world experience and are the only hemophilia therapies developed using Fc fusion technology, which enables them to use the body's natural pathway to prolong the time the therapies remain in the body.

These therapies and rFIXFc-XTEN are part of Biogen's hemophilia business, which Biogen plans to spin off into Bioverativ, an independent, public company focused on the discovery, research, development and commercialization of treatments for hemophilia and other rare blood disorders. Bioverativ will continue to collaborate with Sobi on their joint development programs.

Select Presentation Information:

- *ELOCTATE/ALPROLIX-Focused:*
  - Longitudinal Analysis of Long-term Safety and Efficacy of Recombinant Factor VIII Fc Fusion Protein (rFVIIIFc) in Adults/Adolescents with Severe Hemophilia A – Session: 322, Disorders of Coagulation or Fibrinolysis: Poster I - #1413 - Saturday, December 3, 5:30-7:30 PM PST
  - Longitudinal Analysis of Long-term Safety and Efficacy of Recombinant Factor VIII Fc Fusion Protein (rFVIIIFc) in Previously Treated Children with Severe Hemophilia A – Session: 322, Disorders of Coagulation or Fibrinolysis: Poster I - #1414 - Saturday, December 3, 5:30-7:30 PM PST
  - Clinical Outcomes in Adults/Adolescents with Hemophilia B Treated Long Term with Recombinant Factor IX Fc Fusion Protein (rFIXFc) Prophylaxis: Interim Results of the B-YOND Extension Study – Session: 322, Disorders of Coagulation or Fibrinolysis: Poster I - #1416 - Saturday, December 3, 5:30-7:30 PM PST
  - Long-term Efficacy and Quality of Life With Recombinant Factor VIII Fc Fusion Protein (rFVIIIFc) Prophylaxis in Pediatric, Adolescent, and Adult Subjects with Target Joints and Severe Hemophilia A – Session: 322, Disorders of Coagulation or Fibrinolysis: Poster III - #3791 – Monday, December 5, 6:00-8:00 PM PST
- *Biogen's rFIXFc-XTEN:*
  - Evaluation of rFIXFc-XTEN bleeding efficacy in Hemophilia-B mouse models – Session: 321, Blood Coagulation and Fibrinolytic Factors: Poster III - #3757 – Monday, December 5, 6:00-8:00 PM PST

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. Hemophilia B occurs in about one in 25,000 male births annually, and more rarely in females. The World

Federation of Hemophilia estimates that approximately 180,000 people are currently diagnosed with hemophilia A and B worldwide [1]

People with hemophilia A or B experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening hemorrhages. Prophylactic infusions of factor VIII or IX can temporarily replace the clotting factors that are needed to control bleeding and prevent new bleeding episodes.[2] The World Federation of Hemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.[3]

About ELOCTATE®/ELOCTA®
ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is a recombinant clotting factor therapy developed for hemophilia A using Fc fusion technology to prolong circulation in the body. It is engineered by fusing factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling ELOCTATE to use a naturally occurring pathway to extend the time the therapy remains in the body. While Fc fusion technology has been used for more than 15 years, Biogen and Swedish Orphan Biovitrum AB (publ) (Sobi) have optimized the technology and are the first companies to utilize it in the treatment of hemophilia. ELOCTATE is manufactured using a human cell line in an environment free of animal and human additives.

ELOCTATE is approved in the United States, Japan, Canada, Australia, New Zealand, Brazil, and other countries, and Biogen has marketing rights in these regions. It is also approved in the European Union, Switzerland, Iceland, Liechtenstein, Norway and other countries where it is approved as ELOCTA® and marketed by Sobi.

As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur in the treatment of hemophilia A. Inhibitor development has been observed with ELOCTATE/Elocta, including in previously untreated patients. For more information, please see the full U.S. prescribing information for ELOCTATE. Note that the indication for previously untreated patients in not included in the EU Product Information for ELOCTA.

About ALPROLIX®
ALPROLIX® [Coagulation Factor IX (Recombinant), Fc Fusion Protein], is a recombinant clotting factor therapy developed for hemophilia 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). ALPROLIX is manufactured using a human cell line in an environment free of animal and human additives.

ALPROLIX is approved for the treatment of hemophilia B in the United States, Japan, Canada, Australia, New Zealand, Brazil and other countries, and Biogen has marketing rights in these regions. It is also approved in the European Union, Iceland, Liechtenstein, Norway and other countries, where it is marketed by Sobi.

Allergic-type hypersensitivity reactions and development of inhibitors have been observed with ALPROLIX in the treatment of hemophilia 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 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/ELOCTA 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, safety profile, and efficacy of ELOCTATE® in hemophilia A and ALPROLIX® in hemophilia B, the potential benefits of pipeline programs, and the proposed spin-off of Biogen's hemophilia business and the timing thereof. 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 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.

References

[1] World Federation of Hemophilia. Annual Global Survey 2015, published in October 2016. Available at: http://www1.wfh.org/publication/files/pdf-1669.pdf.

[2] World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: http://www.wfh.org/en/page.aspx?pid=637. Accessed on November 14, 2016.

[3] World Federation of Hemophilia. Guideline for the management of hemophilia, 2nd edition. Available at: http://www1.wfh.org/publication/files/pdf-1472.pdf. Accessed on December 2015.

Multimedia Files:

Download All Files

Preview image

Download:
Download Thumbnail (3.82 KB)
Download Preview (4.81 KB)
Download Small (16.94 KB)
Download Full Size (30.24 KB)
Download Square (4.9 KB)

Preview image

http://www.sobi.com
Download:
Download Thumbnail (16.49 KB)
Download Preview (19.62 KB)
Download Small (36.78 KB)
Download Full Size (66.07 KB)
Download Square (16.91 KB)

Contact:

BIOGEN:
Media Contact:
Tracy Vineis, +1-781-464-3260
public.affairs@biogen.com
or
Investor Relations Contact:
Susan Altschuller, +1-781-464-2442
IR@biogen.com
or
SOBI:
Media Contact:
Linda Holmström, + 46 708 73 40 95
linda.holmstrom@sobi.com
or
Investor Relations Contact:
Jörgen Winroth, +1-347-224-0819
jorgen.winroth@sobi.com