Biogen Idec and Sobi Present New Data from the Phase 3 Study of Their Long-Lasting Hemophilia Factor Candidate ELOCTATE ™

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-Additional Analyses from Phase 3 A-LONG Study Support Positive Clinical Profile of ELOCTATE for Hemophilia A-

WESTON, Mass. and STOCKHOLM--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Swedish Orphan Biovitrum AB (publ) (Sobi) (STO: SOBI) presented new data that support the clinical and safety profile of their long-lasting recombinant factor VIII candidate ELOCTATE* for hemophilia A. Five platform and oral presentations at the XXIV International Society on Thrombosis and Haemostasis (ISTH) Congress in Amsterdam, The Netherlands, highlight the new FVIII candidate's potential to reduce the number of intravenous injections people with hemophilia A require, its efficacy in controlling bleeding during and after surgery, and its efficacy in treating acute bleeding episodes.

"We are excited to share these new data, which include patients' and physicians' assessment of ELOCTATE's efficacy in treating bleeding episodes and in controlling bleeding during surgery," said Glenn Pierce, M.D., Ph.D., senior vice president of Global Medical Affairs and chief medical officer of Biogen Idec's hemophilia therapeutic area. "The A-LONG data presented at ISTH support the potential of ELOCTATE to enable longer intervals between prophylactic (preventative) injections compared to the current standard of care."

Treatment of Bleeding

An evaluation of the treatment of acute bleeding episodes across the prophylaxis and episodic (on demand) treatment arms of the phase 3 A-LONG study showed that more than 87% of bleeds were controlled with a single injection of ELOCTATE and more than 97% of were controlled with two or fewer injections. These data were showcased in the e-poster presentation:

- *Treatment of Bleeding Episodes in Subjects with Haemophilia A With Long-Lasting Recombinant Factor VIII Fc Fusion Protein (rFVIIIFc) in the Phase 3 A-Long Study*

Novel Assay Clinical Research

For the first time Biogen Idec shared results of evaluations of the performance of ELOCTATE when evaluated using two investigational hemostasis assays. Results from a large scale, global clinical evaluation of ELOCTATE by thrombin generation assay (TGA), using a standardized sample collection procedure and an optimized and validated assay performed at a central laboratory showed that, despite inherent patient-to-patient differences in thrombin generation activity, ELOCTATE and Advate** showed equivalent thrombin generation potential post-infusion. ELOCTATE also showed prolonged thrombin generation activity relative to Advate, correlating with the pharmacokinetic data observed in these subjects.

Results from a rotation thromboelastometry (ROTEM®) analysis conducted on 44 patients treated with ELOCTATE from 13 A-LONG study sites showed that ELOCTATE was fully active in patient samples. Additionally, the FVIII activity as measured by clotting time seen for ELOCTATE at 72 hours after dosing was comparable to the activity of Advate at 48 hours after dosing (mean clotting times of 1,238 seconds and 1,213 seconds, respectively).

The data presentations were consistent with conventional assay results from the A-LONG study. These data were showcased in two oral platform presentations:

- *Evaluation of The Thrombin Generation Potential of a Recombinant Factor VIII Fc Fusion Protein in a Phase III Multi-National Clinical Trial*
- *Evaluation of Whole Blood Clotting Activity of Recombinant Factor VIII Fc Fusion Protein by ROTEM Analysis in a Multi-Center Phase 3 Clinical Trial*

Surgery Analysis

Results from an analysis of the phase 3 A-LONG study showed that ELOCTATE consistently controlled bleeding during and after 9 major surgeries in 9 patients with hemophilia A. Physicians reported high efficacy levels of ELOCTATE during surgery, with hemostasis (the stoppage of bleeding) rated as "excellent" for 8/9 surgeries and "good" for 1/9 surgeries. According to the investigators' analysis, the results were comparable to that for similar surgeries in people without hemophilia. These data were showcased in the e-poster presentation:

- *Long-Lasting Recombinant Factor VIII Fc Fusion (rFVIIIFc) for Perioperative Management of Subjects with Haemophilia A in the Phase 3 A-LONG Study*

Population Pharmacokinetics (PK) Analysis

Analysis of a population pharmacokinetics (popPK) model developed for ELOCTATE demonstrate that the model accurately predicts peak and trough factor VIII activity levels achieved in the A-LONG clinical study at a variety of ELOCTATE doses. These data were showcased in the e-poster presentation:

- *Population Pharmacokinetic Analysis of Long-Lasting Recombinant Factor VIII Fc Fusion Protein (rFVIIIFc) in Patients with Severe Haemophilia A*

“These new data from the A-LONG study show potential for the application of Fc fusion technology in hemophilia,” said Birgitte Volck, M.D., Ph.D., senior vice president development and chief medical officer of Sobi. “We are excited to share these data on ELOCTATE, which provide additional evidence of the potential of ELOCTATE to make a meaningful difference in the lives of patients with hemophilia A.”

ELOCTATE Global Regulatory Status

A Biologics License Application (BLA) for Biogen Idec’s long-lasting hemophilia product candidate ELOCTATE is currently under review with the FDA for the treatment of hemophilia A. If approved, ELOCTATE would be the first major treatment advance for the hemophilia A community in more than two decades.

A Marketing Application for ELOCTATE has been submitted in Australia for the treatment of hemophilia A. Additional regulatory filings are planned.

About the Fc Fusion Technology Platform

ELOCTATE is a clotting factor under development using Biogen Idec’s novel and proprietary monomeric Fc fusion technology, which makes use of a naturally occurring pathway that delays the breakdown of factor in the body and cycles it back into the bloodstream, resulting in a longer circulating half-life. Fc fusion technology is used in seven FDA-approved products for the treatment of chronic diseases including rheumatoid arthritis, psoriasis and platelet disorders. Biogen Idec is the first and only to apply this proprietary technology to hemophilia.

About Hemophilia A

Hemophilia A is a rare, inherited 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 is caused by having substantially reduced or no factor VIII activity, which is needed for normal blood clotting. People with hemophilia A experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening hemorrhage. Injections of factor VIII can restore the coagulation process, control bleeding, and prevent new bleeding episodes. The Medical and Scientific Advisory Council of the National Hemophilia Foundation recommends prophylaxis as the optimal therapy for people with severe hemophilia A. Currently, prophylaxis in hemophilia A typically requires injections three times per week or every other day to maintain a sufficient circulating level of clotting factor.

About the Biogen Idec and Sobi Collaboration

Biogen Idec and Swedish Orphan Biovitrum (Sobi) are partners in the development and commercialization of ELOCTATE in hemophilia A and ALPROLIX in hemophilia B. Biogen Idec leads development, has manufacturing rights, and has commercialization rights in North America and all other regions excluding the Sobi territory. Sobi has the right to opt in to assume final development and commercialization in Europe (including Russia), the Middle East and Northern Africa.

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, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world’s oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than $5 billion in annual revenues. 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. Our 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 three late stage biological development projects within hemophilia and neonatology. We also market 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 2012, Sobi had total revenues of SEK 1.9 billion (€ 215 M) and about 500 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 impact and therapeutic effect of our long-lasting hemophilia product candidates and regulatory filings. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. 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, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates, 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.

**ELOCTATE™ Antihemophilic Factor (Recombinant Fc Fusion Protein)*
***Advate® [antihemophilic factor (recombinant), plasma/albumin-free method] is a registered trademark of Baxter International Inc.*

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