New Phase 3 Data Confirm Long-Lasting Characteristics Of ALPROLIX™ and ELOCTATE ™ Across Multiple Hemophilia Populations

December 9, 2013

– Interim Analyses from Phase 3 Pediatric Studies Suggest Prolonged Half-Life of Investigational Long-Lasting Therapies in Children Under Age 12 –

CAMBRIDGE, Mass. & STOCKHOLM--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ:BIIB) and Swedish Orphan Biovitrum AB (publ) (Sobi) (STO:SOBI) announced new results from Phase 3 studies of their investigational long-lasting recombinant factor IX and VIII Fc fusion protein candidates for hemophilia B and A, ALPROLIX™ and ELOCTATE™, including an interim analysis of pediatric pharmacokinetics (PK) data. These interim data are the first to demonstrate that ALPROLIX and ELOCTATE have consistently prolonged half-lives (a measure of the time therapy circulates in the bloodstream) in children, compared to study participants' prior therapies. Investigators presented these results, which were consistent with PK results in adults and adolescents, at the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans, held on December 7 to 10.

ALPROLIX and ELOCTATE use a technology called Fc fusion and demonstrate prolonged circulation in the body, which has been shown in studies of adults with hemophilia to extend the time between prophylactic infusions.

"As seen in adult studies, interim data demonstrated that in children, the use of Fc fusion technology prolongs the half-lives of these experimental therapies," said Guy Young, M.D., director, Hemostasis and Thrombosis Center, Children's Hospital Los Angeles. "We are investigating whether prophylactic dosing intervals longer than the currently available therapy are possible with these treatments. The frequency of traditional prophylactic regimens is a significant challenge for parents of children with hemophilia, many of whom require infusions multiple times per week."

Kids B-LONG and Kids A-LONG are ongoing, multi-center Phase 3 studies of ALPROLIX and ELOCTATE for previously treated children under age 12 with hemophilia B and A, respectively. Kids B-LONG and Kids A-LONG are designed to investigate the safety, efficacy and PK of ALPROLIX and ELOCTATE. In Kids B-LONG, the mean half-life of ALPROLIX was more than three times longer than currently available factor IX therapies. The Kids A-LONG interim analysis showed the mean half-life of ELOCTATE was approximately one and a half times that of existing factor VIII therapies. For both ALPROLIX and ELOCTATE, prolonged half-lives were seen in each age group analyzed – under six and six to under 12 years old.

In 43 children treated with ELOCTATE as of February 8, 2013, and 23 children receiving ALPROLIX as of April 23, 2013, no inhibitors (antibodies that may interfere with the activity of the therapy) were detected. Overall, the pattern of treatment-emergent adverse events reported was typical of the populations studied, with no unique safety issues identified.

Final results of the pediatric studies will evaluate the safety and efficacy of ALPROLIX and ELOCTATE, as well as provide further PK information. Investigators plan to report these results at a future medical meeting. The primary endpoint for both studies is the occurrence of inhibitor development over the study period. Secondary outcome measures include the annualized bleeding rate (ABR), or projected number of yearly bleeding episodes, and assessments of response to treatment.

At the meeting, new analyses of data from B-LONG and A-LONG, the Phase 3 studies of ALPROLIX and ELOCTATE in adolescents and adults, were presented. These data provided additional insight into the prophylactic dosing regimens that may be possible with these therapies, if approved. Prophylaxis regimens involve regularly scheduled infusions designed to prevent or reduce bleeding episodes. In these studies, a prolonged half-life helped study participants achieve effective prevention or reduction of bleeding episodes with fewer prophylactic infusions.

"These data underscore our commitment to advancing scientific understanding and innovation in hemophilia, and our goal of introducing the first long-lasting therapies to those with hemophilia," said Glenn Pierce, M.D., Ph.D., senior vice president of Global Medical Affairs and chief medical officer at Biogen Idec's hemophilia therapeutic area. "These analyses add to the growing body of data supporting the clinical benefits of ALPROLIX and ELOCTATE in people of different ages with hemophilia B and A, and their potential to reduce bleeding episodes with fewer prophylactic infusions, if approved."

Less Frequent Prophylactic Dosing Observed with ELOCTATE

A post-hoc analysis of A-LONG participants who were receiving a prophylactic (preventive) regimen with currently available factor VIII therapies prior to the study, evaluated self-reported dose, dose interval and bleeding rates over the preceding 12 months while on currently approved factor VIII therapies. These data points were also collected for on-study ELOCTATE therapy.

The majority of participants reported infusions three times a week with their previous factor VIII therapy. During the study, 98.8 percent of participants had ELOCTATE prophylactic dosing regimens with less frequent infusions than they reported using before the study. Their last on-study prophylactic dosing intervals were every three days (36.3 percent), twice weekly (28.8 percent), every four days (5.0 percent) and every five days (30.0 percent). Overall, these participants reported a median of 6.0 bleeding episodes in the prior year with their existing therapy; in the last three months of on-study ELOCTATE therapy, they had a median annualized bleeding rate of zero. Weekly factor consumption for prophylaxis remained consistent with ELOCTATE and prior therapy for the majority of participants.

"Prophylactic dosing schedules have the potential to be less frequent and reduce bleeding episodes with the emergence of long-lasting therapy," said Birgitte Volck, M.D., Ph.D., senior vice president development and chief medical officer of Sobi. "These data may help physicians understand how prophylactic dosing schedules could differ between investigational, long-lasting ELOCTATE therapy and currently available factor VIII treatments. The post-hoc analysis showed that ELOCTATE enabled bleeding control for study participants with less frequent prophylactic infusions than their previous therapy."

Study investigators reported that ELOCTATE was well tolerated, and no inhibitors were detected during the A-LONG study. Safety events were representative of those occurring in the general hemophilia population. Outside of the perioperative (surgical) period, the most common adverse events (incidence of greater than or equal to five percent) included nasopharyngitis (common cold), arthralgia (joint pain), headache and upper

respiratory infection.

Hemophilia Quality of Life Measure Validated

This study evaluated the reliability, validity and sensitivity of the Hemophilia-Specific Quality of Life Index (Haem-A-QoL), a 46-item questionnaire used to assess health-related quality of life specifically in people with hemophilia. The analysis used EuroQoL-5 Dimension (EQ-5D) data to validate Haem-A-QoL data collected from participants in the A-LONG and B-LONG studies. EQ-5D is a quality-of-life health assessment tool that is commonly used in late-stage studies for other diseases. These data further validate the usefulness of the Haem-A-QoL measurement in adults with hemophilia.

"Without adequate control over bleeding episodes, hemophilia not only leads to physical complications, but also may impact a person's ability to attend work or school, enjoy leisure activities or maintain positive mental health," said Aoife Brennan, M.D., senior medical director, Clinical Development of Biogen Idec's hemophilia therapeutic area. "To understand these effects, we are committed to examining the impact of our investigational therapies ALPROLIX and ELOCTATE on a broad range of measurements, including quality-of-life measurement tools. A preliminary analysis of Haem-A-QoL scores in A-LONG and B-LONG showed numerical improvements in total scores from baseline, and we are conducting further analyses to understand the potential clinical implications of these results."

About ALPROLIX and ELOCTATE

ALPROLIX and ELOCTATE are investigational fully recombinant, long-lasting clotting factor therapies being developed for hemophilia B and A, respectively. They use Fc fusion technology, which takes advantage of a naturally occurring pathway that delays the breakdown of Immunoglobulin G Subclass 1, or IgG1 (protein commonly found in the body), and cycles it back into the bloodstream. The Fc portion of IgG1 is fused to factors IX and VIII in ALPROLIX and ELOCTATE, respectively. This technology is thought to be responsible for the prolonged time ALPROLIX and ELOCTATE circulate in the body. While Fc fusion is an established technology that has been used for more than 15 years, Biogen Idec is the only company to apply it in hemophilia.

Based on Phase 3 study results, prophylactic therapy with ALPROLIX and ELOCTATE may help prevent or reduce bleeding episodes in people with severe hemophilia B and A, respectively. Regulatory applications for both therapies are currently under review in several countries including the United States, Canada and Australia.

About Hemophilia A and B

Hemophilia 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 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 3,300 people in the United States. According to the World Federation of Hemophilia, an estimated 400,000 people worldwide are living with hemophilia.

Hemophilia A is caused by having substantially reduced or no factor VIII activity, while hemophilia B is caused by having substantially reduced or no factor IX activity; factor VIII and factor IX are needed for normal blood clotting. 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. 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.

About the Biogen Idec and Sobi Collaboration

Biogen Idec and Swedish Orphan Biovitrum (Sobi) are partners in the development and commercialization of ALPROLIX for hemophilia B and ELOCTATE for hemophilia A. 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 ALPROLIX and ELOCTATE, our investigational long-lasting recombinant factor product candidates. 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 data or 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.

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Contact:

BIOGEN IDEC:
Media Contact:
Todd Cooper, +1 781 464 3260
public.affairs@biogenidec.com
or
Investor Relations Contact:
Ben Strain, +1 781 464 2442
IR@biogenidec.com
or
SWEDISH ORPHAN BIOVITRUM:
Media Contact:
Charlotte af Klercker, +46 70 729 7327
Charlotte.afklercker@sobi.com
or
Analyst/Investor Contact:
Jörgen Winroth, +46 8 697 2135