BIOGEN IDEC AND SOBI ANNOUNCE POSITIVE TOP-LINE RESULTS FROM PHASE 3 STUDY INVESTIGATING LONG-LASTING RECOMBINANT FACTOR IX FC FUSION PROTEIN IN HEMOPHILIA B

September 26, 2012

-- Prophylactic regimens resulted in low single-digit annualized bleeding rates --

-- Median dosing interval was 14 days in the individualized interval prophylaxis arm during the last 6 months on study --

-- Greater than 90% of bleeding episodes were controlled by a single injection of rFIXFc --

-- No patients developed inhibitors to rFIXFc --

-- The primary efficacy and safety objectives were met and Biogen Idec plans to submit a BLA to US FDA in first half 2013 --

WESTON, Mass. and STOCKHOLM, Sweden--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Swedish Orphan Biovitrum (Sobi) (STO: SOBI) today announced positive results from B-LONG, a clinical study that evaluated a new long-lasting clotting factor candidate in people with hemophilia B. Hemophilia B is a rare inherited disorder that impairs blood coagulation.

Top-line results from B-LONG, a global, multi-center, Phase 3 clinical study of the companies' long-lasting recombinant Factor IX Fc fusion protein (rFIXFc), showed that rFIXFc was effective in the control and prevention of bleeding, routine prophylaxis, and perioperative management. Recombinant FIXFc was generally well-tolerated. Additional analyses of the B-LONG study are ongoing and the companies anticipate presenting further results at a future scientific meeting.

Biogen Idec plans to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in the first half of 2013. Consistent with guidelines published by the European Medicines Agency (EMA) that require a study in children less than 12 years of age prior to filing, Biogen Idec and Sobi expect to file a Marketing Authorization Application with the EMA upon completion of the ongoing Kids B-LONG study.

"The results of the B-LONG study offer the potential for longer-lasting protection from bleeding for patients with hemophilia B," 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. "Currently, prophylactic treatment of hemophilia B requires intravenous injections up to three times a week, which makes the prospect of a longer-lasting Factor IX therapy very exciting."

"Our companies are pioneering the application of Fc fusion technology to extend the half-life of clotting factors. Fc fusion technology utilizes a naturally-occurring recycling pathway that has been successfully employed in other therapeutic areas. This approach holds promise for combining more consistent protection with fewer injections," said Geoffrey McDonough, M.D., Chief Executive Officer of Sobi. "The B-LONG study results are highly encouraging and support the potential use of this technology in hemophilia B."

Summary of Key Data from B-LONG

In the B-LONG study, 123 male patients aged 12 years and older were enrolled. The B-LONG study had four treatment arms: weekly prophylaxis, individualized interval prophylaxis, episodic treatment and perioperative management (Arms 1, 2, 3 and 4, respectively).

Overall, 93.5 percent of patients completed the study. Recombinant FIXFc was generally well-tolerated. No inhibitors to rFIXFc were detected and no cases of anaphylaxis were reported in any patients, all of whom switched from commercially-available Factor IX products. One serious adverse event was assessed to be possibly related to drug by the investigator. The patient experienced obstructive uropathy in the setting of hematuria; he continued rFIXFc treatment and the event resolved with medical management.

The most common adverse events (incidence of ≥5 percent) occurring outside of the perioperative management arm (i.e., Arms 1, 2 and 3, but not Arm 4) were nasopharyngitis, influenza, arthralgia (joint pain), upper respiratory infection, hypertension and headache.

The overall median annualized bleeding rates (including spontaneous and traumatic bleeds) were 2.95 in the weekly prophylaxis arm, 1.38 in the individualized interval prophylaxis arm, and 17.69 in the episodic treatment arm. In the individualized interval prophylaxis arm, the median dosing interval during the last 6 months on study was 14 days.

Control of bleeding was assessed in all patients who experienced a bleeding episode during the study. Overall, 90.4 percent of bleeding episodes were controlled by a single injection of rFIXFc.

Recombinant FIXFc was assessed in the perioperative management of 12 patients undergoing 14 major surgical procedures. The treating physicians rated the hemostatic efficacy of rFIXFc as excellent or good in 100 percent of these surgeries.

B-LONG included a pharmacokinetic (PK) analysis of rFIXFc in all patients in the study. In a protocol-defined subset of patients with extensive PK sampling, the approximate terminal half-life of rFIXFc was 82 hours compared to 34 hours for BeneFIX® [Coagulation Factor IX (Recombinant)].

About the B-LONG Study and the rFIXFc Program

B-LONG was a global, open-label, multi-center Phase 3 study that evaluated the efficacy, safety and pharmacokinetics of intravenously-injected rFIXFc. The study was designed to evaluate rFIXFc in the control and prevention of bleeding, routine prophylaxis and perioperative management in patients with hemophilia B. B-LONG involved 50 hemophilia treatment centers in 17 countries on 6 continents, and is the largest registrational study conducted in hemophilia B.

The B-LONG study had four treatment arms. In Arm 1 (weekly prophylaxis; n=63), patients were treated weekly with a starting dose of 50 IU/kg, which was adjusted to maintain trough factor levels sufficient to prevent bleeding. In Arm 2 (individualized interval prophylaxis; n=29), patients were treated with 100 IU/kg, at an initial interval of 10 days, which was subsequently individualized to maintain trough factor levels sufficient to prevent bleeding. In Arm 3 (episodic treatment; n=27), patients received rFIXFc episodic treatment as needed for bleeding. In Arm 4 (perioperative management; n=12 patients), rFIXFc was evaluated in the surgical setting; 8 patients in the surgery arm were also enrolled in other treatment arms.

The primary efficacy and safety measures were the annualized bleeding rate and the incidence of adverse events and inhibitor development in patients studied for up to 77 weeks. Secondary endpoints included response to treatment of bleeding episodes and the pharmacokinetics of rFIXFc versus BeneFIX®.

Ongoing clinical studies of rFIXFc include the Kids B-LONG and the B-YOND studies. Kids B-LONG is a Phase 3, open-label study in previously treated children with hemophilia B under age 12, which is actively recruiting patients. B-YOND is a long-term open-label extension study for patients who completed the B-LONG study or who complete the Kids B-LONG study.

About the Fc Fusion Technology Platform

Recombinant FIXFc is a clotting factor developed using Biogen Idec's novel and proprietary monomeric Fc fusion technology, which makes use of a natural pathway to recycle rFIXFc in circulation and enable it to remain in the body longer. With this technology, rFIXFc is designed to provide long-lasting protection from bleeding and reduce the treatment burden associated with hemophilia B, which currently requires more than 100 injections annually for prophylaxis with commercially-available Factor IX products. Fc fusion technology is used in seven FDA-approved products for the long-term treatment of chronic diseases including rheumatoid arthritis, psoriasis and platelet disorders.

Using the same Fc fusion technology, Biogen Idec and Sobi are also developing a long-lasting recombinant Factor VIII Fc fusion protein (rFVIIIFc) for the control and prevention of bleeding episodes and routine prophylaxis in hemophilia A. Top-line results from the A-LONG study are expected later this year. For more information on Biogen Idec's hemophilia research programs, visit www.biogenidechemophilia.com.

About Hemophilia B

Hemophilia B is a rare, inherited disorder in which the ability of a person's blood to clot is impaired. Hemophilia B occurs in about one in 25,000 male births annually and is caused by having substantially reduced or no Factor IX activity, which is needed for normal blood clotting. People with hemophilia B therefore need injections of Factor IX to restore the coagulation process and prevent frequent bleeds that could otherwise lead to pain, irreversible joint damage and life-threatening hemorrhages. The Medical and Scientific Advisory Council of the National Hemophilia Foundation recommends prophylaxis as the optimal therapy for people with severe hemophilia B. Currently, prophylaxis in hemophilia B typically requires injections up to three times per week to maintain a sufficient circulating level of clotting factor.

About the Biogen Idec and Sobi Collaboration

Biogen Idec and Sobi are partners in the development and commercialization of rFIXFc and rFVIIIFc. 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 healthcare company dedicated to bringing innovative therapies and services to improve the lives of rare disease patients. The product portfolio is primarily focused on inflammation and genetic diseases, with three late stage biological development projects within hemophilia and neonatology. Sobi also markets more than 40 products for companies in the specialty and rare disease space. In 2011, Sobi had revenues of SEK 1.9 billion and around 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

Safe Harbor

This press release contains forward-looking statements, including statements about the development and commercialization of long-lasting hemophilia therapies and regulatory filings. These statements may be identified by words such as "believe," "expect," "may," "plan," "will" and similar expressions, and are based on the companies' current beliefs and expectations. Drug development and commercialization involve a high degree of risk. Factors which could cause actual results to differ materially from the companies' 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 our drug candidates, or the companies may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with Biogen Idec's drug development and commercialization activities, please review the Risk Factors section of Biogen Idec's 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 the companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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