New Biogen Hemophilia Data At ISTH Congress to Highlight Extension Study Outcomes and Pediatric Use

June 18, 2015

- Full Results from ALPROLIX® Pediatric Study to Be Released For the First Time -

- Interim Findings to be Presented from ASPIRE, a Long-Term Extension Study with ELOCTATE® in Adults and Children with Hemophilia A -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) will present 23 company-sponsored platform and poster presentations at the International Society on Thrombosis and Haemostasis (ISTH) 2015 Congress, taking place in Toronto, Canada, June 20-25. The data to be presented underscore the company's ongoing commitment to hemophilia through continued research with its available therapies and early-stage programs.

Data presentations include a late-breaking platform presentation from the Kids B-LONG study detailing the safety and efficacy of ALPROLIX® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] in children with hemophilia B. This is the first time the full results from the Kids B-LONG study will be publicly presented. Additionally, an interim ASPIRE study analysis is focused on the long-term safety and efficacy of ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] for the prevention and treatment of bleeding in previously treated adults and adolescents with hemophilia A. ASPIRE is a multi-year extension study for people who completed the pivotal, phase 3 A-LONG or Kids A-LONG studies.

"The breadth of our research presentations at ISTH reflects our commitment to advancing science and improving care for people with hemophilia," said Wing-Yen Wong, M.D., vice president, Global Medical, Hematology and Immunology at Biogen. "We believe that the comprehensive, growing body of ELOCTATE and ALPROLIX clinical data will continue to help clinicians understand the benefits of these therapies as they work with their patients to make treatment decisions."

ELOCTATE and ALPROLIX are the first approved hemophilia A and B therapies to provide bleeding protection with the potential to extend the interval between prophylactic infusions. They were developed using a process called Fc fusion, which was designed to prolong a therapy's circulation in the body using a naturally occurring pathway. While Fc fusion has been used for more than 15 years, Biogen is the only company to apply it to the treatment of hemophilia.

Highlights of Biogen's data for presentation include:

ELOCTATE-Focused Abstracts

- Safety and Efficacy of Recombinant Factor VIII Fusion Protein (rFVIIIFc) for the Prevention and Treatment of Bleeding in Previously-Treated Adult and Adolescent Subjects with Hemophilia A: Interim Analysis of the ASPIRE Study – Poster #235 – *Monday, June 22, 5:30-6:15 p.m. ET*
- Treatment of Bleeding with Recombinant Factor VIII Fc Fusion Protein in Previously-Treated Pediatric Subject with Hemophilia A in the Phase 3 Kids A-LONG Study – Poster #239 – *Monday, June 22, 5:30-6:15 p.m. ET*
- Indirect Comparisons of Factor Consumption, Bleeding Rates, and Infusion Frequencies During Routine Prophylaxis with Recombinant Factor VIII Fc Fusion Protein and Other Recombinant Factor VIII Products – Poster #170 – *Monday, June 22, 5:30-6:15 p.m. ET*

ALPROLIX-Focused Abstracts

- Study of Recombinant Factor IX Fc Fusion Protein in Children with Hemophilia B – Late Breaking Oral Session #009 – *Wednesday, June 24, 8:45-9:00 a.m. ET*
- Indirect Comparisons of Factor Consumption, Bleeding Rates, and Infusion Frequencies During Routine Prophylaxis with Recombinant Factor IX Fc Fusion Protein and Other Recombinant Factor IX Products – Poster #171 – *Monday, June 22, 5:30-6:15 p.m. ET*

Full session details and data presentation listings for the 2015 Congress can be found on the ISTH website at https://www.isth.org/page/2015Microsite/.

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.

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 ELOCTATE

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 and Japan. It is indicated in the United States for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with hemophilia A. ELOCTATE is not indicated for the treatment of a bleeding disorder called von Willebrand disease. ELOCTATE was developed by fusing B-domain deleted factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG_1 (a protein commonly found in the body). It is believed that this enables ELOCTATE to use a naturally occurring pathway to prolong the time the therapy remains in the body.

Common adverse reactions (incidence of greater than or equal to 1 percent) reported in the registrational A-LONG study were arthralgia (joint pain) and malaise (general discomfort). For additional important safety information, and the United States full prescribing information, please visit www.ELOCTATE.com.

About ALPROLIX

ALPROLIX® [Coagulation Factor IX (Recombinant), Fc Fusion Protein], the first recombinant clotting factor therapy with prolonged circulation in the body, is approved in the United States, Canada, Australia and Japan. It is indicated in the United States for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with hemophilia B. ALPROLIX is not indicated for immune tolerance induction therapy, which is a treatment for people with inhibitors, and should not be used in individuals with a known history of serious allergic reactions. ALPROLIX was developed by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG_1). It is believed that this enables ALPROLIX to use a naturally occurring pathway to prolong the time the therapy remains in the body.

Common adverse reactions (incidence of greater than or equal to 1 percent) from the registrational B-LONG study were headache and oral paresthesia (an abnormal sensation in the mouth). For additional important safety information, and the United States full prescribing information, please visit www.ALPROLIX.com.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. 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 product labeling, press releases and additional information about the company, please visit www.biogen.com.

About the Biogen and Sobi Collaboration

Biogen and Swedish Orphan Biovitrum (Sobi) are collaborators in the development and commercialization of ALPROLIX for the treatment hemophilia B and ELOCTATE for the treatment of hemophilia A. Biogen leads development, has manufacturing rights, and has commercialization rights in North America and all other regions excluding the Sobi territory. Sobi has final development and commercialization rights for ELOCTATE in the Sobi territories (essentially, Europe, North Africa, Russia and certain countries in the Middle East) and the right to opt-in to assume final development and commercialization of ALPROLIX in the Sobi territories.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the potential therapeutic impact of ELOCTATE and ALPROLIX. 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 refuse 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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