Biogen Idec Submits Application to FDA for First Long-Lasting Factor VIII Therapy for Hemophilia A

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Half-life of rFVIIIFc may enable prophylactic dosing once to twice weekly

WESTON, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) announced today that the company has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the marketing approval of recombinant factor VIII Fc fusion protein (rFVIIIFc) for the treatment of hemophilia A. Recombinant FVIIIFc is the first hemophilia A product candidate in a new class of long-lasting clotting factor therapies being developed with the goal of reducing the burden of treatment for this condition. If approved, rFVIIIFc will be the first major advance in hemophilia A treatment in more than two decades. The regulatory submission was based on results from A-LONG, the largest registrational phase 3 clinical study in hemophilia A to date.

"This regulatory submission marks another significant step toward our goal of transforming the care of hemophilia for patients, families and caregivers," 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. "In our phase 3 study, patients treated with rFVIIIFc were able to inject rFVIIIFc once-weekly to twice-weekly, which creates the potential for those currently on prophylactic treatment to reduce injections by 50 to 100 per year. Moreover, patients currently treating bleeding episodes could potentially dose prophylactically once per week and maintain significant protection from bleeding with about the same total number of injections each year they use to treat bleeding episodes today."

Typically, prophylaxis in hemophilia A requires injections three times per week or every other day to maintain a sufficient circulating level of clotting factor to provide protection from bleeding. Without prophylactic treatment, people with hemophilia A remain at risk of bleeding episodes that can cause irreversible joint damage and life threatening hemorrhages.

On March 4, 2013 Biogen Idec announced the FDA accepted for review the company's BLA for its factor IX candidate, rFIXFc, for use in patients with hemophilia B.

About the Fc Fusion Technology Platform

Recombinant FVIIIFc is a clotting factor developed using Biogen Idec's novel and proprietary monomeric Fc fusion technology, which makes use of a naturally occurring pathway that delays the destruction of factor and cycles it back into the bloodstream, resulting in a longer circulating half-life.

With this technology, rFVIIIFc is designed to provide long-lasting protection from bleeding and reduce the treatment burden associated with hemophilia A, which currently can require approximately 150 to 180 injections annually for prophylaxis with commercially available factor VIII 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.

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 therefore need injections of factor VIII 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 A.

About the Biogen Idec and Sobi Collaboration

Biogen Idec and Swedish Orphan Biovitrum (Sobi) are partners in the development and commercialization of rFIXFc in hemophilia B and rFVIIIFc in 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.

Safe Harbor

This press release contains forward-looking statements, including statements about the dosage, commercialization and impact of long-lasting hemophilia therapies 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.

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