Sobi and Biogen's ELOCTA® (rFVIIIFc) Approved in Europe for the Treatment of Haemophilia A

November 24, 2015

First therapy to provide prolonged bleeding protection with prophylactic injections every three to five days

Product to launch in initial EU countries in early 2016

STOCKHOLM & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Swedish Orphan Biovitrum AB (publ) (Sobi) (STO: SOBI) and Biogen (NASDAQ: BIIB) today announced that the European Commission (EC) has approved ELOCTA® (rFVIIIFc) for the treatment of haemophilia A in all 28 European Union (EU) member states, as well as Iceland, Liechtenstein and Norway. ELOCTA, a recombinant factor VIII Fc fusion protein with an extended half-life, will be the first haemophilia A treatment in the EU to offer prolonged protection against bleeding episodes with prophylactic injections every three to five days.

"The EC's approval of ELOCTA is an important milestone for the global haemophilia A community, offering the potential to improve the care of haemophilia A across the EU," said Birgitte Volck, M.D., Ph.D., senior vice president of Development and chief medical officer of Sobi. "Our focus is now to ensure timely and sustainable access to ELOCTA for people living with haemophilia A throughout Europe."

ELOCTA is indicated for both on-demand and prophylaxis treatment of people with haemophilia A of all ages. The EC approval was based on data from ELOCTA's pivotal, phase 3 A-LONG clinical study, which demonstrated the efficacy, safety and pharmacokinetics of rFVIIIFc in previously treated males 12 years of age and older with severe haemophilia A, and from the phase 3 Kids A-LONG clinical study, which demonstrated the efficacy and safety of rFVIIIFc in previously treated male children with haemophilia A under 12 years of age. The adverse drug reactions with an incidence of ≥ 0.5 percent for ELOCTA were arthralgia, malaise, myalgia, headache and rash.

"ELOCTA is the first meaningful treatment advance in haemophilia A in nearly 20 years and reinforces our commitment to improving the care of people with this disease around the world," said Gilmore O'Neill, M.D., senior vice president Drug Innovation Units at Biogen. "Since the therapy's approval in the United States last year, we have seen the benefits that extended protection against bleeds can offer people with haemophilia A, and we are excited to work with Sobi to make this innovative therapy available to people in Europe."

Sobi and Biogen are collaborators in the development and commercialization of rFVIIIFc for haemophilia A. Last year, Sobi exercised its opt-in right to assume rFVIIIFc's final development and commercialization in pre-specified territories, which essentially include Europe, North Africa, Russia and certain countries in the Middle East. Biogen leads development and manufacturing of the product and holds commercialization rights in North America and all other regions in the world outside of the Sobi territories.

ELOCTA is the trade name for rFVIIIFc in Sobi's territory, which is also approved under the name ELOCTATE ® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] for the treatment of haemophilia A in the U.S., Canada, Australia, New Zealand and Japan.

About ELOCTA®

ELOCTA (rFVIIIFc) is the first recombinant clotting factor VIII therapy that offers an extended half-life in the body. It is indicated for the treatment and prophylaxis of bleeding episodes in patients with haemophilia A (factor VIII deficiency) and can be used by people of all ages. ELOCTA was developed by fusing B-domain deleted factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). It is believed that this enables ELOCTA to utilize a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion technology has been used in other therapies for more than 15 years, Sobi and Biogen are the first companies to utilize it in the treatment of haemophilia. Allergic type hypersensitivity reactions and development of Factor VIII neutralizing antibodies (inhibitors) may occur following administration of ELOCTA.

About Haemophilia A

Haemophilia A is a rare, chronic, genetic disorder in which the ability of a person's blood to clot is impaired due to missing or reduced levels of a protein known as factor VIII. People with haemophilia A experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening hemorrhages. According to the World Federation of Haemophilia, an estimated 140,000 people worldwide are identified as living with haemophilia A.[1]

Therapies for haemophilia A, the most common form of haemophilia, can be administered either on a schedule to help prevent or reduce bleeding episodes (prophylaxis) or to control bleeding when it occurs (on-demand). The World Federation of Haemophilia recommends that prophylaxis be the goal of therapy because it may prevent bleeding and joint destruction. As a result, regular prophylactic treatment may slow progression of joint disease and may improve quality of life. [2]

About Sobi

Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products for partner companies across Europe, the Middle East, North Africa and Russia. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. 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 more information, please visit www.biogen.com and follow us on Twitter.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the potential benefits of ELOCTA® in hemophilia A, and planned timing of commercial launch in Europe. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. You should not place undue reliance on these statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including uncertainty of success in commercialization of ELOCTA, which may be impacted by, among other things, slower than anticipated acceptance of ELOCTA by patients and the medical community, competition in the hemophilia market, the effectiveness of sales and marketing efforts, problems with the manufacturing process for ELOCTA, the occurrence of adverse safety events, difficulties in obtaining or changes in the availability of reimbursement for our products, failure to obtain regulatory approvals in other jurisdictions, failure to protect intellectual property and other proprietary rights, product liability claims and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). 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.

[1] **World Federation of Hemophilia. Annual Global Survey 2013. http://www1.wfh.org/publications/files/pdf-1591.pdf. Accessed September 2015.**

[2] **World Federation of Hemophilia, WFH Guidelines for the Management of Hemophilia, http://www.wfh.org/en/resources/wfh-treatment-guidelines. Accessed November 2015.**

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