PRESS RELEASE

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Sobi and Biogen receive positive opinion from CHMP for Alprolix® (rFIXFc) for the treatment of haemophilia B

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO: SOBI) and Biogen (NASDAQ: BIIB) received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending that marketing authorisation be granted for Alprolix® (rFIXFc), a recombinant factor IX Fc fusion protein therapy for the treatment of haemophilia B. If approved, Alprolix would be among the first therapies in the European Union (EU) to offer people living with haemophilia B prolonged protection against bleeding episodes with prophylactic dosing intervals.

“This positive opinion marks an important step in our efforts to bring treatment innovation to people with haemophilia in Europe and around the world,” said Krassimir Mitchev, M.D., Ph.D., vice president and medical therapeutic area head of Haemophilia at Sobi. “We are already seeing the benefits that Fc fusion technology can offer through our recent EU launch of Elocta® for people with haemophilia A. We are excited at the prospect of also offering the possibility for prolonged protection and reduced treatment burden to the haemophilia B community with Alprolix.”

The positive opinion was based on results from two global, Phase 3 clinical trials that demonstrated the efficacy, safety and pharmacokinetics of Alprolix for haemophilia B: the pivotal B-LONG study for previously treated adults and adolescents, and the Kids B-LONG study for previously treated children under age 12. The CHMP's recommendation is now referred to the European Commission (EC), which is responsible for granting marketing authorisation for medicines in the EU.

“Therapies that offer prolonged protection from bleeds are changing the way many approach treatment of haemophilia,” said Gilmore O’Neill, M.D., senior vice president, Drug Innovation Units at Biogen. “We are proud to work with Sobi to continue bringing to Europe these innovative Fc fusion therapies, which are grounded in the most robust real-world experience of any prolonged circulation factor therapies to date.”

Sobi and Biogen are collaboration partners in the development and commercialisation of Alprolix for haemophilia B. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Biogen leads development and manufacturing for Alprolix and has commercialisation rights in North America and all other regions in the world excluding the Sobi territory.

About Haemophilia B

Haemophilia B is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting.[1] The World Federation of Hemophilia estimates that approximately 28,000 people are currently diagnosed with haemophilia B worldwide.[2]

People with haemophilia B may experience bleeding episodes in joints and muscles that cause pain, decreased mobility and irreversible joint damage. In the worst cases, these bleeding episodes can cause organ bleeds and life-threatening haemorrhages. Infusions of factor IX temporarily replace clotting factors necessary to resolve bleeding and, when used prophylactically, to prevent new bleeding episodes.[1]

About Alprolix®

Alprolix is a recombinant clotting factor therapy developed for haemophilia B by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables Alprolix to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion has been used for more than 15 years, Sobi and Biogen are the first companies to utilise it in the treatment of haemophilia.

Alprolix is currently approved for the treatment of haemophilia B in the U.S., Canada, Japan, Australia and New Zealand, where it was the first haemophilia B therapy approved to provide prolonged protection from bleeds. As with any infused protein, allergic type hypersensitivity reactions and development of inhibitors may occur following administration of Alprolix.

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. Follow us on Twitter.

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 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

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[1] World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: http://www.wfh.org/en/page.aspx?pid=637#Difference_A_B. Accessed on: February 11, 2016

[2] World Federation of Hemophilia. Report on the Annual Global Survey 2013. Available at: http://www1.wfh.org/publications/files/pdf-1591.pdf. Accessed on: February 11, 2016.

Biogen Safe Harbour

This press release contains forward-looking statements, including statements about the potential benefits of ALPROLIX, and its potential approvability in the EU. 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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