

PRESS RELEASE

Stockholm, 2 December 2013



Sobi's partner Biogen Idec receives notification from FDA of PDUFA date extension for ALPROLIX™

Swedish Orphan Biovitrum AB's (publ) (Sobi) partner Biogen Idec announced today that the U.S. Food and Drug Administration (FDA) has extended the initial Prescription Drug User Fee Act (PDUFA) date for its review of the Biologics License Application (BLA) for ALPROLIX, the company's investigational long-lasting recombinant factor IX Fc fusion protein candidate for hemophilia B. The PDUFA date has been extended by three months, which is the standard extension period.

In response to a request from FDA, Biogen Idec submitted additional information related to the validation of a manufacturing step for ALPROLIX. Due to the timing of this submission, the FDA extended the PDUFA date to allow additional time for review of the marketing application.

The updated timeline for FDA approval will not impact Sobi's planned European approval timelines.

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About ALPROLIX and the Fc Fusion Technology Platform

ALPROLIX is an investigational fully recombinant, long-lasting clotting factor therapy in late-stage clinical development for the treatment of haemophilia B. ALPROLIX uses Fc fusion technology, which makes use of a naturally occurring pathway that delays the breakdown of IgG1 (protein commonly found in the body) and cycles it back into the bloodstream. The Fc portion of IgG1 is fused to factor IX in ALPROLIX and is thought to be responsible for the prolonged time ALPROLIX circulates in the body, which may extend the time between prophylactic infusions. While Fc fusion is an established technology that has been used for more than 15 years, Biogen Idec is the only company to apply it in hemophilia.

ALPROLIX is also under review by regulatory authorities in several countries, including Canada, Australia and Japan.

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About Haemophilia B

Haemophilia B is a rare, chronic, inherited disorder in which the ability of a person's blood to clot is impaired. Haemophilia B occurs in about one in 25,000 male births annually, and more rarely in females. It is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting. People with haemophilia B experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening haemorrhage. Prophylactic infusions of factor IX can temporarily replace clotting factors necessary to control bleeding and prevent new bleeding episodes. The Medical and Scientific Advisory Council of the National Haemophilia Foundation recommends prophylaxis as the optimal therapy for people with severe haemophilia B.

About the Biogen Idec and Sobi Collaboration

Biogen Idec and Swedish Orphan Biovitrum (Sobi) are partners in the development and commercialization of ALPROLIX in haemophilia B. 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 Sobi

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on inflammation and genetic diseases, with three late stage biological development projects within haemophilia and neonatology. We also market a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2012, Sobi had total revenues of SEK 1.9 billion (€ 215 M) and about 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

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, haemophilia 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 labelling, press releases and additional information about the company, please visit www.biogenidec.com.

For more information – not for publication

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