



PRESS RELEASE

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Biogen and Sobi receive positive opinion from CHMP for Elocta™ (rFVIII Fc) for the treatment of Haemophilia A

[Biogen](#) (NASDAQ: BIIB) and [Swedish Orphan Biovitrum AB](#) (publ) (Sobi) (STO: SOBI) received a positive recommendation from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for the marketing authorisation of Elocta™ (rFVIII Fc). Elocta is a recombinant factor VIII Fc fusion protein product for the treatment of haemophilia A that, if approved, would be the first haemophilia A treatment with prolonged circulation available in the European Union (EU).

The positive opinion was based on results from the pivotal, phase 3 A-LONG clinical study, which examined the efficacy, safety and pharmacokinetics of rFVIII Fc 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 evaluated the efficacy and safety of rFVIII Fc in previously treated male children with haemophilia A under 12 years of age. The Committee's positive opinion is now referred to the European Commission (EC), which grants marketing authorisation for medicines in the EU.

"The CHMP's recommendation to approve Elocta is an important milestone in potentially bringing this innovative therapeutic option to people with haemophilia A across Europe," said Aoife Brennan, M.D, vice president of Hematology, Clinical Development at Biogen. "The potential of Elocta to provide protection against bleeding episodes with fewer prophylactic infusions will, if approved, represent the first treatment advance in nearly 20 years for Europe's hemophilia community."

Elocta is the European trade name for rFVIII Fc, which is also known as Eloctate® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] in the U.S., Canada, Australia, New Zealand and Japan, where it is approved for the treatment of haemophilia A. Commonly reported adverse drug reactions (>= 1% of subjects) in the clinical studies were arthralgia, malaise, myalgia, headache and rash. Development of Factor VIII neutralising antibodies (inhibitors) may occur following administration of Elocta.

Biogen and Sobi are collaboration partners in the development and commercialisation of Elocta/Eloctate for haemophilia A. Last year, Sobi exercised its opt-in right to assume final development and commercialisation of Elocta in the Sobi territory (essentially, Europe, North Africa, Russia and certain countries in the Middle East). Biogen leads development for Elocta/Eloctate, has manufacturing rights, and has commercialisation rights in North America and all other regions in the world excluding the Sobi territory.



“We are committed to bringing meaningful treatment advances to the haemophilia community in Europe and worldwide,” said Birgitte Volck, M.D., Ph.D., senior vice president of Development and chief medical officer of Sobi. “We welcome the news of this positive CHMP opinion and look forward to the EC’s forthcoming Elocta decision.”

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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 haemorrhages. According to the World Federation of Hemophilia, an estimated 140,000 people worldwide are identified as living with haemophilia A.¹

About the A-LONG clinical study

The phase 3 A-LONG clinical study was an open-label, multi-centre study involving 165 previously treated males 12 years of age and older with severe haemophilia A. The study evaluated individualised and weekly prophylaxis to reduce or prevent bleeding episodes, and on-demand dosing to treat bleeding episodes. In the individualised arm, each study participant started on a twice-weekly dosing regimen. Participants’ pharmacokinetic parameters were used to guide adjustments to dosing interval (every three to five days), and dose (25 to 65 IU/kg) to target a minimum factor VIII level of 1 to 3 IU/dL or higher as needed to prevent and control breakthrough bleeding episodes. In the study, the dose in the weekly prophylaxis arm was 65 IU/ kg/week.

About the Kids A-LONG clinical study

The Kids A-LONG study is the first clinical study to evaluate an investigational haemophilia therapy with a prolonged half-life in children younger than 12 years of age. The study was a global, open-label, multi-centre Phase 3 study involving 71 boys with severe haemophilia A with at least 50 prior exposure days to factor VIII therapies.

Participants in both the A-LONG and Kids A-LONG clinical trials were able to enrol in ASPIRE, a phase 3, open-label extension study evaluating the long-term safety and efficacy of Eloctate. For more information about these studies, please visit www.biogen.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 haemophilia therapies. For product labelling, press releases and additional information about the company, please visit www.biogen.com.

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 Haemophilia, Inflammation and Genetic diseases. We also market a portfolio of specialty and rare disease products for partner companies across Europe, the Middle

¹ World Federation of Hemophilia. Annual Global Survey 2012. <http://www1.wfh.org/publications/files/pdf-1574.pdf>. Accessed July 2015.



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.

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