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The Republic of Ireland switches all people with haemophilia A & B treated with replacement clotting factors to Sobi's™ extended half-life therapies

The Republic of Ireland has become the first country in Europe where every person with haemophilia will have access to the newest generation of haemophilia treatments, extended half-life therapies, under new supply contracts signed between the HSE (Health Services Executive) and Sobi™.

A new contract for the supply of Elocta® (efmoroctocog alfa), for the treatment of haemophilia A was signed in January 2018. It follows an earlier contract for the supply of Alprolix® (eftrenonacog alfa), for the treatment of haemophilia B. Both Elocta and Alprolix are extended half-life treatments approved for all age groups in the EU. The Fc-fusion molecule is utilising a natural recycling pathway in the body and the safety profiles of the products are supported by post marketing experience from thousands of patients and during a period of more than three years.

With both of these two-year contracts, the Republic of Ireland becomes the first country in Europe to switch an entire population undergoing treatment from conventional short-acting therapies to extended half-life therapies for haemophilia A and B. Steve Bojakowski, Sobi's Patient Access Lead for the UK and the Republic of Ireland, says "With the outcome of the adjudication of both of these tenders, Sobi has demonstrated our desire to provide access to these innovative products in a very sustainable manner."

The Republic of Ireland procurement team has adopted the World Federation of Hemophilia's guidelines for national tenders for the purchase of clotting factor concentrates. Under the guidelines, the tender process for the Alprolix and Elocta contracts included doctors and patients in the product evaluation process. The tender scorecard for the contracts placed emphasis on clinical needs and attributes.

One key criterion in the tender was security of supply. Philip Wood, Head of Haemophilia at Sobi says the company's robust supply infrastructure played an important role. "For people with a life-long disease such as haemophilia, long-term security of supply is vital. Our ability to secure sustainable patient access is part of our ongoing commitment to the haemophilia community."

About haemophilia A and B

Haemophilia is a rare, genetic disorder in which the ability of a person's blood to clot is impaired. Haemophilia A occurs in about one in 5,000 male births annually, and more rarely in females. Haemophilia B occurs in about one in 25,000 male births annually, and more rarely in females. The World Federation of Hemophilia estimates that approximately 180,000 people are currently diagnosed with haemophilia A and B world-wide[i].

People with haemophilia A and B experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening haemorrhages. Prophylactic injections of factor VIII and factor IX can temporarily replace the clotting factors that are needed to control bleeding and prevent new bleeding episodes[ii]. The World Federation of Hemophilia (WFH) recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction[iii].

About Elocta®

Elocta® (efmoroctocog alfa) is a recombinant clotting factor therapy developed for haemophilia A using Fc fusion technology to prolong circulation in the body. It is engineered by fusing factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling Elocta to use a naturally occurring pathway to extend the time the therapy remains in the body (half-life). Elocta is manufactured using a human cell line in an environment free of animal and human additives.

Elocta is approved and marketed by Sobi for the treatment of haemophilia A in the EU, Iceland, Norway, Liechtenstein, Switzerland, Kuwait and Saudi Arabia. It is approved and marketed as ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] by Bioverativ in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, where Bioverativ has the marketing rights.

As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur in the treatment of haemophilia A. Inhibitor development has been observed with Elocta, including in previously untreated patients. Note that the indication for previously untreated patients is not included in the EU Product Information for Elocta.

About Alprolix®

Alprolix® (eftrenonacog alfa), is a recombinant clotting factor therapy developed for haemophilia B using Fc fusion technology to prolong circulation in the body. It is engineered by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling Alprolix to use a naturally occurring pathway to extend the time the therapy remains in the body (half-life). Alprolix is

manufactured using a human cell line in an environment free of animal and human additives.

Alprolix is approved and marketed by Sobi for the treatment of haemophilia B in the EU, Iceland, Norway, Liechtenstein, Switzerland, Kuwait, and Saudi Arabia, as well as in the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries where Bioverativ has the marketing rights.

Allergic-type hypersensitivity reactions and development of inhibitors have been observed with Alprolix in the treatment of haemophilia B, including in previously untreated patients. Note that the indication for previously untreated patients is not included in the EU Product Information.

About the Sobi and Bioverativ collaboration

Sobi and Bioverativ collaborate on the development and commercialisation of Alprolix and Elocta/ELOCTATE. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Bioverativ has final development and commercialisation rights in North America and all other regions in the world excluding the Sobi territory, and has manufacturing responsibility for Elocta/ELOCTATE and Alprolix. While Fc fusion technology has been used for more than 15 years, Sobi and Bioverativ have optimised the technology and are the first companies to utilise it in the treatment of haemophilia.

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 across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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[i] World Federation of Hemophilia, Annual Global Survey 2015, published in October 2016. Available at: http://www.wfh.org/en/data-collection

[ii] 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: June 17, 2016.

[iii] Guideline for the management of hemophilia, World Federation of Hemophilia, 2nd edition, http://www1.wfh.org/publication/files/pdf-1472.pdf. Accessed on December 2015

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