



PRESS RELEASE

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Successful Elocta bid means increased access for people with haemophilia A in the UK

Through an agreement with National Health Service (NHS) and [Sobi™](#), people living with haemophilia A in the United Kingdom will have increased access to Elocta (efmoroctocog alfa) following a successful bid in the United Kingdom's haemophilia A tender.

Efmoroctocog alfa is licensed by the European Commission in all age groups for treatment and prophylaxis (prevention) of bleeding in patients with haemophilia A.¹ It is an extended half-life (EHL) therapy reimbursed by NHS England and as well, suitable for all age ranges and all severities.

“Today’s announcement is exciting news for the haemophilia A community in the UK. The agreement ensures continued and increased access to Elocta for people living with haemophilia A of all ages and all severities”, said Philip Wood, Head of Haematology and Head of Northern Europe at Sobi.

Previously many people living with haemophilia A in the UK had restricted access to efmoroctocog alfa with a finite volume available under the previous agreement. The new agreement is an important step forward for haemophilia A treatment, allowing physicians to prescribe the most suitable therapies and tailor approaches for patients to protect against bleeds and joint damage.

Treatment guidelines recently published by the *British Society for Haematology (BSH)* recommend that prophylactic treatment should be tailored to suit individual daily activity.² EHL therapies have the potential to reduce injection frequency, increase treatment adherence, improve outcomes and potentially allow for a more active lifestyle.³

“Our Liberate Life vision means putting people living with haemophilia and how they want to lead their lives at the front of clinical decision making. People with haemophilia should feel able to live more active lives, through an approach tailored to their specific needs, activity levels and aspirations,” continued Wood.

The new framework agreement will commence on 1 July 2020 and will be operational for two years, with an option to extend for a further 24 months.

About haemophilia A

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. The World Federation of Hemophilia estimates that approximately 170,000 people are currently diagnosed with haemophilia A world-wide. People with haemophilia A 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. The World Federation of Hemophilia (WFH) recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.

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 Sanofi in the United States, Japan and Canada. It is also approved in Australia, New Zealand, Brazil and other countries, where Sanofi 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 Sobi

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,400 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi's revenues amounted to SEK 14.2 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com.

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¹ ELOCTA® Summary of Product Characteristics. Available at <https://www.medicines.org.uk/emc/product/5100/smpc>. Last accessed June 2020

² Rayment et al. Guidelines on the use of prophylactic factor replacement for children and adults with Haemophilia A and B. 2020: 6, 7.

<https://b-s-h.org.uk/guidelines/guidelines/the-use-of-prophylactic-factor-replacement-for-children-and-adults-with-haemophilia-a-and-b/>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6130100/>