Favourable paediatric data results in Alprolix ® product information update

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) today announced that the European Commission has approved an update to the Alprolix® (eftrenonacog alfa) Summary of Product Characteristics (SmPC) to include additional information regarding use among previously untreated patients (PUPs) with haemophilia B. Alprolix is now the only extended half-life factor IX (FIX) product with safety and efficacy data in PUPs included in the SmPC. The data reinforces its favourable safety profile for use in all age groups.

Philip Wood, Head of Haematology at Sobi, welcomed the news: “Today’s announcement not only marks an important milestone for the substantial body of evidence demonstrating the efficacy and safety of Alprolix for all ages, it also reaffirms Sobi’s longstanding dedication to the haemophilia community by supporting patients and physicians to make informed decisions about treatment.”

The SmPC update is based on the PUPs B-LONG study (NCT02234310), in which Alprolix was well tolerated and effective for both prophylaxis and treatment of bleeding episodes. The overall inhibitor incidence was within the expected range. Importantly, only one patient out of 33 developed a low-titre inhibitor, and no high-titre inhibitors were reported.

“One of our core commitments at Sobi is continuously strengthening evidence for the use of Alprolix through clinical data and real-world outcomes. We know this is an essential part of making confident treatment decisions on the basis of outcomes so patients can live lives beyond haemophilia,” said Wood.

The updated product information applies to all EU/EEA countries.

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 1,500 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi's revenue 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.

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, Kuwait, Liechtenstein, Norway, Saudi Arabia and Switzerland. It is also approved in the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries where Sanofi 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. For more information, please see the full prescribing information for Alprolix.

About PUPs B-LONG

PUPs B-LONG (NCT02234310) was an open-label, multicentre, multinational, phase 3 study including male PUPs aged <18 years with haemophilia B (≤2 IU/dL endogenous FIX) to receive rFIXFc. The primary endpoint was occurrence of inhibitor development and secondary endpoints included annualised bleeding rate (ABR) and assessment of response to treatment of bleeding episodes with rFIXFc.

About the Sobi and Sanofi collaboration

Sobi and Sanofi 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). Sanofi 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 Sanofi have optimised the technology and are the first companies to utilise it in the treatment of haemophilia. In September 2019, Sobi exercised early opt-in for the development and commercialisation of BIVV001, an investigational factor VIII therapy with the potential to provide high sustained factor activity levels with once-weekly dosing for people with haemophilia A.

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