PRESS RELEASE

Stockholm, Sweden, 19 May 2023

EMA validates marketing authorisation application for efanesoctocog alfa for treatment of haemophilia A

Sobi today announced that the European Medicines Agency (EMA) has accepted and validated a marketing authorisation application for efanesoctocog alfa, a new class of high-sustained FVIII developed for the treatment of people with haemophilia A of all age groups. The application is based on data from the pivotal XTEND-1 phase 3 study in adults and adolescents and the XTEND-Kids paediatric study in patients <12 years of age.Efanesoctocog alfa was approved by the US Food and Drug Administration (FDA) as ALTUVIIIO earlier this year.

"Sobi aims to raise the standard of care for rare disease patients around the globe," said Tony Hoos, MD, PhD, Head of Research & Development and Chief Medical Officer. "Today's announcement may represent a crucial step towards improving the lives of people with haemophilia A through a potential new treatment option. We look forward to working closely with EMA during their review of our dossier to allow timely access for the haemophilia community in Europe."

Haemophilia A is a rare, genetic disorder in which the ability of a person's blood to clot is impaired due to a lack of factor VIII. Haemophilia A occurs in about one in 5,000 male births annually, and more rarely in females. People with haemophilia can experience bleeding episodes including life-threatening haemorrhages, acute and chronic pain, irreversible joint damage with disability and negative impacts on quality of life. Despite advancements in treatment made in recent years, a large unmet medical need still exists and requires further improvement in the standard of care.

About XTEND-1
XTEND-1 was an open-label, non-randomized interventional study with two parallel assignment arms. Participants in the prophylaxis arm received a weekly prophylactic dose of efanesoctocog alfa for 52 weeks. Participants in on-demand arm received efanesoctocog alfa on demand for 26 weeks followed by a switch to weekly prophylaxis for another 26 weeks. XTEND-1 evaluated efficacy, safety and pharmacokinetics in 159 previously treated patients ≥12 years of age with severe haemophilia A.

About XTEND-Kids
XTEND-Kids was an open-label, non-randomised interventional, single-arm study. Participants received a weekly prophylactic dose of efanesoctocog alfa for 52 weeks. XTEND-Kids evaluates efficacy, safety, and pharmacokinetics in 74 previously treated patients <12 years of age with severe haemophilia A.

About efanesoctocog alfa
Efanesoctocog alfa [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein] (formerly BIVV001) is a novel and investigational recombinant factor VIII therapy with the potential to deliver near-normal factor activity levels for a significant parts of the week, improving bleed protection in a once-weekly dose for people with haemophilia A. Efanesoctocog alfa builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN® polypeptides to extend its time in circulation. It is the only therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on current factor VIII therapies. It was approved as ALTUVIIIO [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] by Sanofi in the US in February 2023. It is not approved in any country outside the US.

About the Sanofi and Sobi collaboration
Sobi and Sanofi collaborate on the development and commercialization of Alprolix® and Elocta®/Eloctate®. The companies also collaborate on the development and commercialisation of efanesoctocog alfa or ALTUVIIIO in the US. 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.

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Sanofi®
Sanofi are an innovative global healthcare company, driven by one purpose: to chase the miracles of science to improve people's lives. Their team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. Sanofi provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the centre of our ambitions. Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY.

Sobi®
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East, Asia and Australia. In 2022, revenue amounted to SEK 18.8 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

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