Once-weekly ALTUVIIIO® approved in Japan as a new class of factor VIII therapy for hemophilia A

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- ALTUVIIIO is a first-in-class, high-sustained factor VIII replacement therapy which provides highly effective bleed protection in adults and children with hemophilia A

- Approval demonstrates commitment to delivering innovation and a paradigm shift in the hemophilia treatment landscape

Paris, September 25, 2023. The Japanese Ministry of Health, Labor, and Welfare (MHLW) has granted marketing authorization for ALTUVIIIO®[Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein], a first-in-class, high-sustained factor VIII replacement therapy. ALTUVIIIO is indicated for control of bleeding tendency in patients with hemophilia A (factor VIII deficiency). ALTUVIIIO was also recently approved by the Taiwan Food and Drug Administration for treatment of adults and children with hemophilia A on August 31, 2023.

Also referred to as efanesoctocog alfa, ALTUVIIIO is the first and only hemophilia A treatment that delivers normal to near-normal factor activity levels (over 40%) for most of the week with once-weekly dosing in adults and adolescents, and significantly reduces bleeds compared to prior factor VIII prophylaxis in adults and adolescents with severe hemophilia A. ALTUVIIIO can be used for routine prophylaxis, on-demand treatment and control of bleeding episodes, and perioperative management of bleeding. The simple recommended dose of 50 IU/kg is intended for all patients and for different clinical scenarios.

Executive Vice President, Global Head of Specialty Care ad interim, Sanofi

> The approval of ALTUVIIIO in Japan and Taiwan represents a major step forward for people living with hemophilia A in those countries. The high-sustained factor activity levels will enable patients and physicians to reimagine living with hemophilia. ALTUVIIIO is a testament to Sanofi's promise to deliver first-in-class best-in-class therapies that can redefine the treatment paradigm and transform the standard of care for people around the world living with hemophilia.

Hemophilia A is a rare, lifelong condition in which the ability of a person's blood to clot properly is impaired, leading to excessive bleeds and spontaneous bleeds into joints that can result in joint damage and chronic pain, and potentially impact quality of life. The severity of hemophilia is determined by the level of clotting factor activity in a person's blood, and there is a negative correlation between risk of bleeding and factor activity levels.

The MHLW approval is based on positive data from patients with severe hemophilia A, including the pivotal XTEND-1 trial in adults and adolescents and data from the XTEND-Kids trial in children under 12 years of age. In the XTEND-1 study, once-weekly ALTUVIIIO prophylaxis (50 IU/kg) met the primary endpoint, providing significant bleed protection for people with severe hemophilia A with a mean annualized bleeding rate (ABR) of 0.71 (95% CI: 0.52 - 0.97) and a median ABR of 0.00 (Q1, Q3: 0.00, 1.04). ALTUVIIIO met the key secondary endpoint with a significant reduction of 77% in ABR versus prior factor VIII prophylaxis based on an intra-patient comparison (95% CI: 58%, 87%).

Data from XTEND-Kids, showed that children younger than 12 years of age receiving once-weekly ALTUVIIIO (50 IU/kg) for 52 weeks (n=73) experienced a mean ABR of 0.6 (95% CI: 0.4 - 0.9) and a median ABR of 0 (Q1, Q3: 0.0 - 1.0). Safety results were consistent with data from the XTEND-1 trial.

Across these studies, ALTUVIIIO has an established safety profile and there were no reports of factor VIII inhibitor development, although inhibitor formation is possible following administration of ALTUVIIIO. The most common side effects (>10%) of ALTUVIIIO are headache and arthralgia.

ALTUVIIIO was first approved in February 2023 by the US Food and Drug Administration. The FDA previously granted Breakthrough Therapy designation in May 2022 — the first factor VIII therapy to receive this designation — Fast Track designation in February 2021, and Orphan Drug designation in 2017. The European Commission granted Orphan Drug designation in June 2019, and the European Medicines Agency accepted the Marketing Authorization Application (MAA) for efanesoctocog alfa in May 2023.

ALTUVIIIO [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein] is a first-in-class high-sustained factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for adults and children with hemophilia A. In adults and adolescents, ALTUVIIIO has a 3- to 4-fold longer half-life relative to standard and extended half-life factor VIII products, providing high-sustained factor activity levels within normal to near-normal range for most of the week, allowing for once-weekly administration. ALTUVIIIO is the first factor VIII therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on earlier generation factor VIII therapies. ALTUVIIIO builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to extend its time in circulation.

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 commercialization of efanesoctocog alfa, or ALTUVIIIO in the US. Sobi has final development and commercialization rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Sanofi has final development and commercialization rights in North America and all other regions in the world excluding the Sobi territory.

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, YouTube.

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

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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in Sanofi’s annual report on Form 20-F for the year ended December 31, 2022. Other than as required by applicable law, Sanofi does not

undertake any obligation to update or revise any forward-looking information or statements.

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