Press Release

FDA approves once-weekly ALTUVIIIO™, a new class of factor VIII therapy for hemophilia A that offers significant bleed protection

Paris and Stockholm – February 23, 2023 – The U.S. Food and Drug Administration (FDA) has approved ALTUVIIIO™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl], previously referred to as efanesoctocog alfa, a first-in-class, high-sustained factor VIII replacement therapy. ALTUVIIIO is indicated for routine prophylaxis and on-demand treatment to control bleeding episodes, as well as perioperative management (surgery) for adults and children with hemophilia A. 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, and significantly reduces bleeds compared to prior factor VIII prophylaxis.

> ***Paul Hudson***
> CEO, Sanofi
> *"Today's approval of ALTUVIIIO allows patients and physicians to reimagine living with hemophilia. The high sustained factor activity levels that can be achieved with ALTUVIIIO have the potential to change the hemophilia landscape. For the first time, with a once-weekly dose, powerful bleed protection is a reality for patients. Significant shifts in treatment paradigms that improve people's lives, like ALTUVIIIO, are what we have committed to delivering at Sanofi."*

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.

> ***Lynn Malec, MD***
> Medical Director of Comprehensive Center for Bleeding Disorders and Associate Investigator at The Versiti Blood Research Institute, and Associate Professor of Medicine and Pediatrics at The Medical College of Wisconsin
> *"This approval marks an important clinical advancement for the hemophilia community because we have an option that can achieve higher levels of factor activity with a single simplified weekly dose. By maintaining high levels of factor activity throughout the week, patients can be confident in the bleed protection ALTUVIIIO offers."*

This is the first approval of ALTUVIIIO. The FDA evaluated the application under Priority Review, which is granted to therapies that have the potential to provide significant improvements in the treatment, diagnosis, or prevention of serious conditions. The FDA previously granted ALTUVIIIO Breakthrough Therapy designation in May 2022 – the first factor VIII therapy to receive this recognition – Fast Track designation in February 2021, and Orphan Drug designation in August 2017.

Regulatory submission in the EU is anticipated in the second half of 2023. The European Commission granted Orphan Drug designation in June 2019.

ALTUVIIIO helps elevate expectations for hemophilia A by providing protection for longer

The FDA approval is based on data from the pivotal XTEND-1 Phase 3 study recently published in *The New England Journal of Medicine*. Once-weekly ALTUVIIIO prophylaxis met the primary endpoint, providing significant bleed protection for people with severe hemophilia A with a mean

annualized bleeding rate (ABR) of 0.70 (95% CI: 0.5-1.0) and a median ABR of 0.0 (Q1, Q3: 0.0, 1.0). ALTUVIIIO met the key secondary endpoint with a significant reduction of 77% in ABR versus prior factor prophylaxis based on an intra-patient comparison (95% CI:58%-87%).

Additional data showed prevention of joint bleeds with a median annualized joint bleeding rate of 0 (Q1, Q3: 0.0, 1.0). Treatment with ALTUVIIIO provided 100% resolution of target joints, which are joints that have recurrent bleeds (e.g., knee, ankle, or elbow). ALTUVIIIO provided mean factor VIII activity greater than 40% for most of the week and greater than 10% at Day 7; these levels were associated with a low bleed risk. In the study, ALTUVIIIO was well-tolerated and inhibitor development to factor VIII was not detected, although is possible following administration of ALTUVIIIO.

Additionally, interim data from XTEND-Kids showed that children younger than 12 years of age receiving once-weekly ALTUVIIIO for 26 weeks (n=23) experienced a mean ABR of 0.5 (95% CI: 0.2-1.3) and a median ABR of 0 (Q1, Q3: 0.0, 1.3). Safety results were consistent with data from the XTEND-1 trial. The full results from XTEND-Kids will be presented at a future medical meeting.

Across the 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 is indicated 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.

To ensure that patients have access to the improved bleed protection provided by ALTUVIIIO, Sanofi will price ALTUVIIIO at parity to the annual cost of treating a prophylaxis patient on Eloctate® [Antihemophilic Factor (Recombinant), Fc Fusion Protein]. Sanofi will also provide comprehensive patient support services and resources online and at 1.855.MyALTUVIIIO (855.692.5888). In the U.S., ALTUVIIIO is expected to be commercially available in April.

About ALTUVIIIO™

ALTUVIIIO [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] is a novel von Willebrand Factor (VWF) independent recombinant factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for adults and children with hemophilia A. ALTUVIIIO has a 3 to 4 fold longer half-life relative to standard and extended half-life factor VIII products. It 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 XTEND Clinical Programs

The XTEND clinical program is comprised of two Phase 3 trials in hemophilia A: XTEND-1 in people 12 years or older and XTEND-Kids in children younger than 12 years old. There is also an ongoing extension study (XTEND-ed).

The Phase 3 XTEND-1 study (NCT04161495) was an open-label, non-randomized interventional study assessing the safety, efficacy, and pharmacokinetics of once-weekly ALTUVIIIO in people 12 years of age or older (n=159) with severe hemophilia A who were previously treated with factor VIII replacement therapy. The study consisted of two parallel treatment arms — the prophylaxis Arm A (n=133), in which patients who had received prior factor VIII prophylaxis were treated with once-weekly intravenous ALTUVIIIO prophylaxis (50 IU/kg) for 52 weeks, and the on-demand Arm B (n=26), in which patients who had received prior on-demand factor VIII therapy began with 26 weeks of on-demand ALTUVIIIO (50 IU/kg), then switched to once-weekly prophylaxis with ALTUVIIIO (50 IU/kg) for an additional 26 weeks.

The primary efficacy endpoint was the mean annualized bleeding rate (ABR) in Arm A, and the key secondary endpoint was an intra-patient comparison of ABR during the ALTUVIIIO weekly prophylaxis treatment period versus the prior factor VIII prophylaxis ABR for a subset of participants in Arm A who had participated in a previous observational study (Study 242HA201/OBS16221).

The XTEND-Kids study (NCT04759131) was an open-label, non-randomized interventional study of the safety, efficacy, and pharmacokinetics of once-weekly ALTUVIIIO in previously treated patients younger than 12 years of age (n=67) with severe hemophilia A. Patients received once-weekly ALTUVIIIO prophylaxis (50 IU/kg) for 52 weeks.

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.

About Sobi®

Sobi is a specialized international biopharmaceutical company transforming the lives of people with rare diseases. Providing sustainable 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 and Asia. 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.

About Sanofi

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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Sanofi Forward-Looking Statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the marketing and other potential of the product, or regarding potential future revenues from the product. Forward-looking statements

are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.