Press Release

Completed XTEND-Kids Phase 3 study strengthens potential of ALTUVIIIO™ to redefine expectations for treatment of children <12 years of age with hemophilia A

Paris, March 2, 2023. The XTEND-Kids phase 3 pivotal study evaluating the safety, efficacy and pharmacokinetics of ALTUVIIIO as once-weekly prophylaxis in previously treated patients <12 years of age with severe hemophilia A met its primary endpoint of safety, with no FVIII inhibitors detected in 74 children, with more than 50 children experiencing at least 50 exposure days, nearly a full year of treatment. The completion of XTEND-Kids represents the final milestone needed for regulatory submission in the EU.

> ***Karin Knobe, MD, PhD***
> Therapeutic Area Head, Rare Diseases and Rare Blood Disorders, Sanofi
> *"At Sanofi, we never settle. We work alongside patients, caregivers, and advocacy organizations to understand the needs of the hemophilia community and pursue first-in-class technologies to meet those needs. We strive for a future where every child with hemophilia can play without fear, travel free from a rigid treatment schedule, and pursue their dreams unencumbered by worry."*

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.

ALUTVIIIO is a first-in-class, high-sustained FVIII therapy approved by the US Food and Drug Administration (FDA) for routine prophylaxis, on-demand treatment and control of bleeding episodes, and perioperative management of bleeding in adults and children in February 2023. Granted Breakthrough Therapy designation by the FDA in May 2022—the first FVIII therapy to receive this designation—ALTUVIIIO also received Fast Track designation in February 2021 and Orphan Drug designation in 2017. The European Commission granted Orphan Drug designation in June 2019.

About XTEND-Kids

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 with severe hemophilia A. Patients received once-weekly ALTUVIIIO prophylaxis (50 IU/kg) for 52 weeks which provided high-sustained FVIII levels throughout the weekly dosing interval with a median (IQR) annualized bleeding rate (ABR) of 0.00 (0.00, 1.02) and an estimated mean (95% CI) ABR of 0.89 (0.56 ; 1.42). The primary endpoint was the occurrence of inhibitor development (baseline to 52 weeks). No inhibitors were detected in this study.

About ALTUVIIIO™

ALTUVIIIO [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] 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. 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 throughout (≥40%) for most of the week and at 15% at the end of the dosing interval. 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. XTEN® is a registered trademark of Amunix Pharmaceuticals, Inc.

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 of XTEND-1 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).

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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 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.

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. 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.