Press Release

Efanesoctocog alfa met primary and key secondary endpoints in pivotal study in hemophilia A, demonstrating superiority to prior factor prophylaxis treatment

- Once-weekly efanesoctocog alfa met primary endpoint in phase 3 study, resulting in a clinically meaningful prevention of bleeding episodes (bleed protection)
- In the key secondary endpoint, efanesoctocog alfa demonstrated superiority in prevention of bleeding episodes, showing a statistically significant and clinically meaningful reduction in annualized bleeding rate compared to prior factor VIII prophylaxis therapy
- Efanesoctocog alfa is a novel and investigational factor VIII therapy designed to provide near-normal factor activity levels for the majority of the week in a once-weekly prophylactic treatment regimen

Paris and Stockholm – March 9, 2022 - Sanofi and Swedish Orphan Biovitrum AB (publ) (Sobi®) (STO:SOBI) today announced positive topline results from the pivotal XTEND-1 Phase 3 study evaluating the safety, efficacy and pharmacokinetics of efanesoctocog alfa (BIVV001) in previously treated patients ≥12 years of age with severe hemophilia A.

The study met the primary endpoint, showing a clinically meaningful prevention of bleeds in people with severe hemophilia A receiving weekly prophylaxis with efanesoctocog alfa over a period of 52 weeks. The median annualized bleeding rate (ABR) was 0 with a mean ABR of 0.71. The key secondary endpoint was also met, demonstrating once-weekly efanesoctocog alfa was superior to prior prophylactic factor VIII replacement therapy, showing a statistically significant reduction in ABR based on intra-patient comparison. Efanesoctocog alfa was well-tolerated, and inhibitor development to factor VIII was not detected. The most common treatment-emergent adverse events (>5% of participants overall) were headache, arthralgia, fall, and back pain.

> ***Dietmar Berger, MD, PhD***
> *Global Head of Development and Chief Medical Officer, Sanofi*
> *"While advances have been made in the treatment of hemophilia, unmet medical needs still exist. These positive topline data, showing a very low annualized bleeding rate, enhance efanesoctocog alfa's potential to transform hemophilia A therapy. We believe efanesoctocog alfa provides higher protection for longer duration with reduced treatment burden of once-weekly dosing, and we look forward to working with regulators to bring this therapy to patients as soon as possible."*

Hemophilia 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. Hemophilia A occurs in about one in 5,000 male births annually, and more rarely in females. People with hemophilia can experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening hemorrhages.

> ***Anders Ullman, MD, PhD***
> *Head of R&D and Chief Medical Officer, Sobi*
> *"We believe once-weekly efanesoctocog alfa has the potential to represent a new class of factor VIII therapy designed to provide high sustained factor VIII levels near normal for the majority of the week. We look forward to sharing these Phase 3 results, including data on physical health, pain and joint health, at future medical meetings."*

The data will be the basis for submission to regulatory authorities around the globe beginning this year. Submission in the EU will follow availability of data from the ongoing XTEND-Kids pediatric study, expected in 2023. Efanesoctocog alfa was granted Orphan Drug Designation by the US Food and Drug Administration (FDA) in August 2017 and the European Commission in June 2019. The US FDA granted Fast Track Designation in February 2021. Efanesoctocog alfa is

currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

About Phase 3 XTEND-1 study

The Phase 3 XTEND-1 study (NCT04161495) is an open-label, non-randomized interventional study assessing the safety, efficacy and pharmacokinetics of efanesoctocog alfa 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 includes two parallel treatment arms – the prophylaxis arm, where study participants received a weekly prophylactic 50 IU/kg dose of efanesoctocog alfa for 52 weeks (Arm A), some of which were enrolled following an observation period on prophylaxis using currently marketed factor VIII replacement therapies, and an on-demand arm, where study participants received 50 IU/kg as needed for 26 weeks followed by weekly prophylaxis for another 26 weeks (Arm B).

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

About efanesoctocog alfa (BIVV001)

Efanesoctocog alfa is a novel and investigational recombinant factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for people with hemophilia A. It 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 first investigational factor VIII therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on current factor VIII therapies. Efanesoctocog alfa is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

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, an investigational factor VIII therapy with the potential to provide high sustained factor activity levels with once-weekly dosing for people with hemophilia A. 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®

Sobi is a specialised 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 2021, revenue amounted to SEK 15.5 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

XTEN® is a registered trademark of Amunix Pharmaceuticals, Inc.

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 and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. 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, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, 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.