Press Release

NEJM publishes once-weekly efanesoctocog alfa Phase 3 data demonstrating its potential to transform the treatment landscape for people with hemophilia A

Paris and Stockholm – January 25, 2023 – Pivotal study data published in *The New England Journal of Medicine (NEJM)* continues to highlight the efficacy, safety, and pharmacokinetic profile of efanesoctocog alfa, an investigational treatment for hemophilia A. These data demonstrate that efanesoctocog alfa delivered normal to near-normal factor activity levels (>40%) for the majority of the week with once-weekly dosing. Efanesoctocog alfa is currently under priority review by the United States Food and Drug Administration (FDA) and the target action date for the decision is February 28, 2023.

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 that can result in joint damage and chronic pain, and potentially impact their quality of life. The severity of hemophilia is determined by the level of clotting factor activity in a person's blood.

Angela Weyand, MD
Investigator of the XTEND-1 Clinical Trial and Associate Professor at Michigan Medicine
"We are excited about the potential for efanesoctocog alfa to address unmet needs by allowing people living with hemophilia to enjoy an active lifestyle. Currently, they often need to make trade-offs between bleed protection and dosing frequency. Based on the XTEND-1 study results assessing efanesoctocog alfa, we have the opportunity to provide near normal factor activity levels for an extended period of time (the majority of a week) with a single dose, which is a first for hemophilia A. The data show that efanesoctocog alfa can offer patients increased bleed protection, leading to improved outcomes, such as reduced pain and improved physical functioning, that may impact daily life with a reduced treatment burden."

The data from the pivotal XTEND-1 Phase 3 study published in *NEJM* show that efanesoctocog alfa met primary and key secondary endpoints, demonstrating clinically meaningful prevention of bleeds and superior bleed protection compared to prior factor VIII prophylaxis based on an intra-patient comparison. Treatment with efanesoctocog alfa prophylaxis resulted in significant and clinically meaningful improvements in physical health, pain, and joint health. Key results include:

- The median and mean annualized bleeding rates (ABR) were 0.00 (IQR: 0.00-1.04) and 0.71 (95% CI: 0.52-0.97), respectively.
- A statistically significant and clinically meaningful reduction in ABR (77%) versus prior factor VIII prophylaxis ($p<0.001$).
- Nearly all (97%) bleeding episodes resolved with a single injection of efanesoctocog alfa (50 IU/kg).
- Efanesoctocog alfa provided mean factor activity >40 IU/dL for the majority of the week and at 15 IU/dL at Day 7.
- Efanesoctocog alfa prophylaxis improved physical health ($p<0.001$), pain intensity ($p=0.03$), and joint health ($p=0.01$) when comparing 52 week and baseline measurements.[i]
- In patients with target joints at baseline, 100% of the target joints were resolved after at least 12 months of continuous prophylaxis.
- 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 at Sanofi

"We are steadfast in our commitment to developing novel treatment options that have a meaningful impact for patients. We are hopeful that Altuviiio (efanesoctocog alfa) will help deliver on this goal by offering unprecedented factor activity levels with once-weekly dosing, fulfilling its potential as a best-in-class therapy for hemophilia A."

Quality of life data from the XTEND-1 study were recently presented at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition. The findings provided further evidence of the potential positive impact of once-weekly efanesoctocog alfa prophylaxis to provide normal to near-normal factor activity levels for the majority of the week, reduce pain, and improve physical functioning for people with hemophilia A.

About Phase 3 XTEND-1 Study (NCT04161495)

The Phase 3 XTEND-1 study (NCT04161495) was an open-label, non-randomized interventional study assessing the safety, efficacy, and pharmacokinetics of once-weekly 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 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 efanesoctocog alfa 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 26 weeks of on-demand efanesoctocog alfa (50 IU/kg), then switched to once-weekly prophylaxis (50 IU/kg) for an additional 26 weeks.

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 factor VIII prophylaxis ABR for participants in Arm A who had participated in a previous observational study (Study 242HA201/OBS16221).

About hemophilia A

Hemophilia A is a rare, genetic disorder in which the ability of a person's blood to clot is impaired due to a missing or defective factor VIII clotting protein. 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. Factor replacement therapy remains a cornerstone of care and can be used across multiple treatment scenarios.

About efanesoctocog alfa

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. Altuviiio™ is the intended trade name of efanesoctocog alfa in the US, but it could differ in other territories as per the local regulatory requirements; formerly known as BIVV001. Efanesoctocog alfa is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

Efanesoctocog alfa is currently under FDA review and the target action date for the decision is February 28, 2023. The FDA also granted efanesoctocog alfa 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, anticipated in the second half of 2023, will follow availability of data from the ongoing, fully recruited XTEND-Kids paediatric study, expected in the first half of 2023. The European Commission granted efanesoctocog alfa orphan designation in June 2019. Sanofi and Sobi® collaborate on the development of efanesoctocog alfa.

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. 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 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.

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.

[i]Physical health was assessed with the Haem-A-QoL Physical Health score. Pain intensity was assessed using the PROMIS Pain Intensity 3a past 7 days intensity of pain at its worst score.

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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.