Press Release

NEJM publishes ALTUVIIIO XTEND-Kids phase 3 data supporting its potential to transform the treatment landscape for children with severe hemophilia A

- ALTUVIIIO provides high-sustained factor levels with once-weekly dosing in children under 12 with hemophilia A
- XTEND-Kids results show highly effective bleed protection in hemophilia A with no inhibitor development to factor VIII

Paris, July 17, 2024 – Full results from the XTEND-Kids phase 3 study published in *The New England Journal of Medicine* (*NEJM*) highlights the efficacy, safety, and pharmacokinetic profile of ALTUVIIIO [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein]. ALTUVIIIO (efanesoctocog alfa), a first-in-class, high-sustained factor VIII replacement therapy, is approved for adults and children with hemophilia A for routine prophylaxis and on-demand treatment to control bleeding episodes as well as for perioperative management (surgery).

> ***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
> *"Children represent a population for which it has been historically difficult to achieve effective bleed prevention and these published results demonstrate an important breakthrough as we strive to optimize the standard of care. Achieving high-sustained factor activity with once-weekly dosing helps mitigate the need to make a tradeoff between the treatment burden of factor replacement therapy and efficacy, which we often witness in treating severe hemophilia."*

The pivotal XTEND-Kids study published in *NEJM* shows ALTUVIIIO met primary and secondary endpoints, which included occurrence of factor VIII inhibitors and annualized bleed rates (ABRs). The results show no inhibitor development to factor VIII was detected with ALTUVIIIO (0% [95% confidence interval (CI)] 0–5]). The median annualized bleed rate (ABR) was 0.00 (interquartile range [IQR]: 0.00-1.02), and the estimated mean (95% CI) ABR was 0.61 (0.42–0.90) in the study of 73 patients treated per protocol. In the pediatric population, clearance of administered factor concentrates from the blood is greater than in adults, often meaning injections are needed 2-4 times per week using standard (SHL) or extended half-life (EHL) factor VIII products.

Prevention of all joint bleeds is critical to maintain joint health throughout life. Eighty-two percent of the children treated with once-weekly ALTUVIIIO had zero joint bleeds, demonstrating ALTUVIIIO weekly prophylaxis has the potential to provide long-term preservation of joint health.

> ***Dietmar Berger, MD, PhD***
> Global Head of Development and Chief Medical Officer at Sanofi
> *"The XTEND-Kids data validate the connection between high-sustained factor activity levels and improved health outcomes, including joint health. Offering a treatment option that emphasizes effective bleed protection in children with hemophilia can help give families increased peace of mind when their loved ones participate in everyday activities. The results are a testament to our scientific expertise and commitment to redefine the standard of care for children living with hemophilia through ALTUVIIIO and our broader portfolio of hemophilia therapies."*

ALTUVIIIO was well-tolerated in children, and no adverse events led to treatment discontinuation. The most common treatment-emergent adverse events (>10%) were SARS-CoV-2 test positive, upper respiratory tract infection, and fever (pyrexia). No serious allergic reactions, anaphylaxis, or embolic or thrombotic events were reported.

About ALTUVIIIO

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, 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.

ALTUVIIIO is currently approved and marketed in the US, Taiwan, and Japan. On June 17, 2024, it was approved by the European Commission for the treatment and prevention of bleeds and perioperative prophylaxis in hemophilia A under the name ALTUVOCT.

ALTUVIIIO is the first factor VIII therapy to receive Breakthrough Therapy Designation by the US Food and Drug Administration in May 2022, Fast Track Designation in February 2021, and Orphan Drug Designation in 2017. The European Commission granted orphan designation in June 2019.

About XTEND-Kids

The XTEND-Kids study (NCT04759131) was an open-label, non-randomized interventional study of once-weekly ALTUVIIIO in previously treated patients younger than 12 years of age with severe hemophilia A. Patients (N=74) received once-weekly ALTUVIIIO (50 IU/kg) prophylaxis for 52 weeks. The primary endpoint was the occurrence of factor VIII inhibitors. Secondary endpoints included annualized bleed rates (ABR) of treated bleeds, bleed treatment, joint health, quality of life, perioperative management, pharmacokinetics, and safety.

An ongoing extension study, XTEND-ed (NCT04644575) is evaluating the long-term safety and efficacy of ALTUVIIIO in previously treated patients with severe hemophilia A for up to four years.

About Hemophilia A

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

About 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, Taiwan, and Japan and ALTUVOCT™ in Europe. 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 1,800 employees across Europe, North America, the Middle East, Asia and Australia. In 2023, revenue amounted

to SEK 22.1 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn .

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 the world, 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

Media Relations

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Nicolas Obrist | + 33 6 77 21 27 55 | nicolas.obrist@sanofi.com
Victor Rouault | + 33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | + 1 516 521 2929 | timothy.gilbert@sanofi.com

Investor Relations

Thomas Kudsk Larsen |+ 44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | + 33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Arnaud Delépine | + 33 6 73 69 36 93 |arnaud.delepine@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Keita Browne | + 1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com
Tarik Elgoutni | + 1 617 710 3587 | tarik.elgoutni@sanofi.com
Thibaud Châtelet | + 33 6 80 80 89 90 | thibaud.chatelet@sanofi.com

---

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 pandemics or other global crises may 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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.