Press Release

Two fitusiran Phase 3 studies published in The Lancet and The Lancet Haematology highlight potential to address unmet needs across all types of hemophilia

- Both Phase 3 studies achieved their primary and secondary endpoints; fitusiran prophylaxis demonstrated significant and clinically meaningful improvements in bleed protection across all hemophilia populations, presented at ASH 2021

Paris – April 4, 2023 – Two studies, published in *The Lancet and The Lancet Haematology*, evaluating the efficacy and safety of fitusiran, an investigational siRNA therapy for the prophylactic treatment of adults and adolescents with hemophilia A or B, reinforce the potential of this investigational therapy to transform the current standard of care and address unmet needs for all types of hemophilia, regardless of inhibitor status.

Hemophilia A and B are rare congenital lifelong bleeding disorders in which the ability of a person's blood to clot is impaired, leading to excessive bleeds and spontaneous bleeds into joints that can result in joint damage and chronic pain, and significantly impact quality of life. Fitusiran has the potential to provide prophylaxis for all types of hemophilia, regardless of inhibitor status, with as few as six subcutaneous injections per year.

> ***Dietmar Berger, M.D., Ph.D.***
> Head of Global R&D ad interim and Chief Medical Officer at Sanofi
> *"Sanofi is committed to advancing the standard of care for all people with hemophilia through innovative science, providing consistent bleed protection while reducing treatment burden. We are entering a new era in hemophilia where, for the first time, people can choose therapies that meet their personal needs. These published data validate our science and add to a growing body of evidence supporting fitusiran's potential to transform the treatment landscape. We look forward to sharing additional data on fitusiran later this year."*

Both Phase 3 studies compared once-monthly subcutaneous fitusiran prophylaxis (80mg) with on-demand/episodic use of clotting factor concentrates in the ATLAS-A/B study, and on-demand/episodic use of bypassing agents in the ATLAS-INH study. Across both clinical studies, prophylactic treatment with fitusiran reduced annualized bleeding rates by 90% (95% CI [84.1%; 93.6%], P <0.0001) compared to the control arms, showing a statistically significant and clinically meaningful improvement in bleeding episodes when compared to on-demand treatments; and showed improvement in quality of life.

In the study ATLAS-INH study published by *The Lancet,* 66% of participants with inhibitors (25 out of 38) receiving fitusiran 80mg monthly experienced zero bleeding episodes compared to 5% (1 out of 19) receiving an on-demand bypassing agent after nine months of treatment.

The ATLAS A/B study published in *The Lancet Haematology* showed 51% of participants without inhibitors (40 out of 79) who received fitusiran 80mg monthly prophylaxis experienced zero bleeds compared to 5% (2 out of 40) in the comparator group, receiving on-demand clotting factor concentrates.

Sanofi is currently investigating the efficacy and safety of fitusiran under a revised regimen which includes lower doses and less frequent dosing (as few as six subcutaneous injections per year), maintaining an antithrombin target range of 15-35% in all ongoing studies.

ATLAS-AB Phase 3 Study

ATLAS-A/B is a Phase 3 randomized, open-label study investigating the efficacy and safety of fitusiran in males ≥12 years with severe hemophilia A or B without inhibitors who had previously been treated with on-demand clotting factor concentrates. Study participants (n=120) were randomized 2:1 to receive either once-monthly 80mg subcutaneous fitusiran prophylaxis or on-demand clotting factor concentrates. The primary endpoint is annualized bleeding rate.

ATLAS-INH Phase 3 Study

The ATLAS-INH study is a randomized, open-label Phase 3 study designed to evaluate the safety and efficacy of fitusiran in males ≥12 years with severe hemophilia A or B with inhibitors to factor VIII or IX. Study participants (n=57) receiving on-demand treatment with bypassing agents (BPA) were randomized in a 2:1 ratio to receive once-monthly 80mg subcutaneous fitusiran prophylaxis or continue with on-demand BPA. The primary endpoint is annualized bleeding rate.

About fitusiran

Fitusiran is an investigational, subcutaneously administered small interference RNA therapeutic in development for the prophylactic treatment of people with hemophilia A or B, with or without inhibitors. Fitusiran is designed to lower antithrombin, a protein that inhibits blood clotting, with the goal of promoting thrombin generation to rebalance hemostasis and prevent bleeds. Fitusiran utilizes Alnylam Pharmaceutical Inc.'s ESC-GalNAc conjugate technology, which enables subcutaneous dosing with increased potency and durability. Fitusiran is currently under clinical investigation and has not been evaluated by any regulatory authority.

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.

Media Relations

Sally Bain | + 1 781 264 1091 | sally.bain@sanofi.com
Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Nicolas Obrist | + 33 6 77 21 27 55 | nicolas.obrist@sanofi.com

Investor Relations

Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com
Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Tarik Elgoutni| + 1 617 710 3587 | tarik.elgoutni@sanofi.com
Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@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 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. 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.