SANOFI

Media Update

Sanofi presents amended protocols in fitusiran clinical studies at EAHAD 2021

February 5, 2021

The amended protocol being implemented for all ongoing adult and adolescent fitusiran clinical studies was presented today at the 14th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD). Fitusiran is an investigational, subcutaneously administered small interference RNA therapy in development for the treatment of people with hemophilia A or B, with or without inhibitors.

Implementation of the amended protocol follows Sanofi's voluntary pause in dosing and enrollment in the ongoing fitusiran clinical studies on October 30, 2020 to allow the investigation of reports of non-fatal thrombotic events in the trials. This assessment included analysis of reported thrombotic events, anti-thrombin levels, and other available clinical data.

Sanofi's priority is the safety of patients. Amendments to the dose and dosing regimen, aimed at further enhancing the benefit-risk profile of fitusiran for patients, were highlighted in the oral presentation. Under the amended protocol, the dose for adults and adolescents will be reduced to 50 mg every other month (six times a year), with the potential to adjust the dose and/or dose frequency based on an individual patient's anti-thrombin levels.

Sanofi has aligned with several health authorities, including the U.S Food and Drug Administration, on the amended protocol; dosing has resumed in certain countries following completion of local requirements. The company continues to engage with health authorities to resume fitusiran dosing worldwide as quickly as possible. Evaluation of dosing in the fitusiran pediatric study is ongoing and therefore, dosing in that study remains paused at this time.

Sanofi is committed to addressing the unmet needs of the global hemophilia community with a goal to break barriers that exist and help raise the standard of care. The company believes fitusiran may transform treatment for people with hemophilia A or B, with or without inhibitors as the only hemophilia prophylactic treatment with the potential for six subcutaneous injections per year.

Editor's Note:
Fitusiran is an investigational, subcutaneously administered, small interference RNA therapeutic in development for the prophylaxis treatment of people with hemophilia A or

B, with or without inhibitors. Fitusiran is designed to target antithrombin, a protein that inhibits blood clotting, with the goal of promoting sufficient thrombin generation to naturally 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

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.