

Sanofi to resume dosing in fitusiran clinical studies in the U.S.

December 10, 2020

Sanofi will resume fitusiran dosing in ongoing U.S. adolescent and adult clinical studies. Fitusiran is an investigational, small interference RNA therapy in development for the treatment of people with hemophilia A or B, with or without inhibitors. Sanofi's first priority is patient safety. The company voluntarily paused dosing in all ongoing fitusiran clinical studies on October 30, 2020 to assess reports of non-fatal thrombotic events in patients participating in the Phase 3 program.

Sanofi promptly completed the assessment of available data and aligned with the U.S. Food and Drug Administration to rapidly resume fitusiran dosing for patients in the adolescent and adult clinical studies. The company will implement amended protocols with an adjusted dose and dosing regimen aimed at further strengthening the benefit-risk profile of fitusiran for patients. Evaluation of dosing in the fitusiran pediatric study is ongoing and therefore, dosing in that study remains paused at this time.

Outside the U.S., Sanofi continues engaging with health authorities to resume fitusiran dosing worldwide, with the protocol amendments, as quickly as possible.

To allow for the appropriate collection and assessment of safety and efficacy data under the amended protocols, the company expects that global regulatory submission timelines for the adult and adolescent studies will be delayed by up to approximately 18 months, subject to alignment with health authorities.

Sanofi is committed to addressing the unmet needs of the global hemophilia community through scientific innovation. The company continues to believe fitusiran has the potential to transform treatment for people with hemophilia A or B, with or without inhibitors.

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

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