Press Release

Qfitlia approved as the first therapy in the US to treat hemophilia A or B with or without inhibitors

- Qfitlia (fitusiran), the first antithrombin-lowering therapy in hemophilia, offers consistent protection with as few as six injections a year via a prefilled pen or vial and syringe
- Unique mechanism helps reduce the frequency of bleeding episodes for people with hemophilia

Paris, March 28, 2025. The US Food and Drug Administration (FDA) has approved Qfitlia (fitusiran), the first antithrombin-lowering (AT) therapy for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients (aged 12 or older) with hemophilia A or B with or without factor VIII or IX inhibitors. The approval is based on data from the ATLAS phase 3 studies that demonstrated clinically meaningful bleed protection as measured by annualized bleeding rates (ABR) across hemophilia patients with or without inhibitors.

Phil Gattone
President and CEO, National Bleeding Disorders Foundation
"Current treatment options can make people with hemophilia feel they need to choose between effective bleed control and convenient dosing schedules, leading to trade-offs when it comes to disease management. Qfitlia takes a novel approach to providing protection for people living with hemophilia while reducing the frequency of dosing for patients and their families."

By lowering AT, a protein that inhibits blood clotting, Qfitlia helps increase thrombin generation to restore hemostasis in people with hemophilia. Qfitlia uses small-interfering RNA technology, which enables low treatment frequency, subcutaneous dosing, and low volume injections.

Brian Foard
Executive Vice President, Head of Specialty Care, Sanofi
"This approval highlights our commitment to advancing innovation and improving care for the rare blood disorders community. Qfitlia has the potential to meaningfully change the hemophilia landscape through effective bleed protection, infrequent dosing, and simplified administration. Our robust portfolio of hemophilia treatment options continues to grow as we focus on offering protection with reduced treatment burden that best fits an individual's needs."

Guy Young, MD
Director, Hemostasis and Thrombosis Center at Children's Hospital, Los Angeles
"Qfitlia delivers the fewest doses of any prophylactic therapy in hemophilia, and its unique mechanism allows it to be used to treat all types of hemophilia, including with inhibitors and hemophilia B, where unmet medical needs remain. By targeting antithrombin, which can be reliably measured with an FDA-cleared blood assay, Qfitlia is proven to help rebalance hemostasis and improve bleed rates and protection."

In the ATLAS clinical development program, Qfitlia demonstrated low bleed rates across subgroups with as few as six injections a year. Key results include:

- Significant bleed reduction by 71% in ABR for patients without inhibitors treated with Qfitlia prophylaxis compared to clotting factor concentrate on-demand (estimated mean: ABR 9.0 vs. 31.4, respectively; $p<0.0001$) and by 73% in ABR compared to bypassing agent on-demand for patients with inhibitors (estimated mean: ABR 5.1 vs. 19.1, respectively; $p=0.0006$)
- Median observed ABR during the open-label extension study was 3.8 (IQR: 0.0–11.2) in patients without inhibitors and 1.9 (IQR: 0.0–5.6) in patients with inhibitors
- Median observed annualized spontaneous bleeding rate during the open-label extension study was 1.9 (interquartile range (IQR): 0.0-7.5) in patients without inhibitors and 1.9 (IQR: 0.0-3.7) in patients with inhibitors

- Nearly half of patients in the open-label extension study experienced one or fewer bleeds (31% 0 bleeds and 47% 0-1 bleeds)

There is also the potential for significant adverse reactions, including thrombotic events, acute and recurrent gallbladder disease, and hepatotoxicity. The most common adverse reactions (incidence >10%) are viral infection, nasopharyngitis, and bacterial infection.

In conjunction with the Qfitlia approval, the FDA also cleared the Siemens Healthineers' INNOVANCE® Antithrombin assay as a companion diagnostic for Qfitlia to measure AT levels. Through the Qfitlia Testing Program with Labcorp, the FDA-cleared companion diagnostic will be available to patients prescribed Qfitlia to measure AT levels at no cost.

Qfitlia can offer the fewest doses of all prophylactic therapies, and it will have a comparable price to other prophylactic hemophilia treatments. HemAssist is launching alongside Qfitlia to provide comprehensive patient support services, including insurance and financial assistance as well as educational resources. This program is for patients prescribed Qfitlia or other hemophilia treatments from Sanofi's portfolio.

The FDA granted Qfitlia Orphan Drug Designation for hemophilia A and B, Fast Track Designation for hemophilia A and B with and without factor VIII or IX inhibitors, and Breakthrough Therapy Designation for hemophilia B with factor IX inhibitors. A regulatory submission for Qfitlia for the treatment of hemophilia A or B in adults and adolescents with or without inhibitors is under review in Brazil. A regulatory decision is expected in China in the second half of 2025.

About hemophilia

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. Hemophilia A and B are caused by a deficiency of factor VIII and IX, respectively, resulting in insufficient thrombin generation and ineffective clot formation, which is further complicated in people who develop inhibitors to their factor treatment.

About the ATLAS clinical development program

The efficacy and safety of Qfitlia is being investigated in the ATLAS clinical development program. The program includes completed phase 3 studies ATLAS-INH (NCT03417102), ATLAS-A/B (NCT03417245), and ATLAS-PPX (NCT03549871). There are three ongoing phase 3 studies ATLAS-NEO (NCT05662319), ATLAS-PEDS (NCT03974113), and ATLAS OLE (NCT03754790).

The ongoing ATLAS-OLE study is a single-arm, phase 3, open-label study evaluating the safety and efficacy of Qfitlia with a revised AT-based dosing regimen (AT-DR), which was designed to maintain an AT target range of 15%-35% in patients who have completed a prior phase 3 ATLAS clinical trial. This study includes lower doses and less-frequent dosing than earlier studies of Qfitlia. The efficacy of Qfitlia AT-DR treatment was assessed by comparing the AT-DR treatment data from ATLAS-OLE to the control data from studies ATLAS-INH and ATLAS-A/B. The analyses follow the intent to treat principle.

About Qfitlia

Qfitlia (fitusiran) is a first-in-class AT lowering therapy approved by the US FDA for prophylactic treatment of adults and pediatric patients (aged 12 and older) living with hemophilia A and B with or without factor VIII or IX inhibitors, and is administered via subcutaneous injection with a convenient, prefilled pen for the 50 mg dose. Qfitlia prevents bleeds and helps rebalance hemostasis by lowering AT, a protein that inhibits blood clotting, to promote thrombin generation. Qfitlia is a small interference RNA therapeutic that utilizes Alnylam Pharmaceutical Inc.'s ESC-GalNAc conjugate technology.

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

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