Press Release

Sanofi's Qfitlia and Cablivi approved in China, expanding care for rare diseases

- Qfitlia, the first antithrombin-lowering therapy for hemophilia, can offer consistent protection with as few as six injections a year
- Cablivi, the first Nanobody medicine, targets acquired/immune-mediated thrombotic thrombocytopenic purpura — a rare, life-threatening blood clotting disorder

Paris, December 11, 2025. The National Medical Products Administration (NMPA) in China has approved two innovative Sanofi medicines for rare hematologic diseases: Qfitlia (fitusiran) for hemophilia and Cablivi (caplacizumab) for acquired thrombotic thrombocytopenic purpura. These approvals mark another step in Sanofi's long-term commitment to China, reinforcing the company's ambition to bring transformative medicines across diverse disease areas. With Qfitlia and Cablivi, Sanofi reaches its fourth and fifth approvals in China this year, following Tzield for stage 2 type 1 diabetes and Sarclisa for two indications in relapsed and newly diagnosed multiple myeloma.

Qfitlia is the first antithrombin (AT)-lowering therapy for routine prophylaxis in people with hemophilia. Qfitlia is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in pediatric patients 12 years of age and older, and adults with severe hemophilia A (coagulation factor VIII deficiency, FVIII<1%) with or without factor VIII inhibitors, or severe hemophilia B (coagulation factor IX deficiency, FIX<1%) with or without factor IX inhibitors.

This 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. 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 injections, and low-volume dosing. Hemophilia affects more than 40,000 people in China.

Cablivi is the first Nanobody targeted therapy designed to treat acquired/immune-mediated thrombotic thrombocytopenic purpura (aTTP/iTTP) in adults and adolescents aged 12 or older weighing at least 40 kg.

This approval brings an innovative medicine specifically indicated for this rare and life-threatening blood clotting disorder to China, where approximately 2700 patients are diagnosed annually. Despite standard treatments, aTTP/iTTP carries a mortality rate of up to 20%. Cablivi targets von Willebrand factor (vWF), a protein in the blood involved in hemostasis, and is designed to inhibit the interaction between vWF and platelets. Used in conjunction with plasma exchange and immunosuppressive therapy, it helps by inhibiting the formation of microthrombi, which contribute to organ damage during the course of the disease.

These two approvals expand Sanofi's rare hematology portfolio in China, addressing critical unmet needs across both chronic bleeding disorders and acute clotting emergencies.

> *"Qfitlia represents a potentially transformative advancement for the hemophilia community in China, shifting care from treating bleeds as they occur to helping prevent them altogether. By offering effective bleed protection and simplified administration, Qfitlia has the potential to make prophylaxis more accessible for people with hemophilia worldwide,"* said **Brian Foard,** Executive Vice President, Head of Specialty Care, Sanofi. *"Cablivi addresses a critical unmet need for patients facing aTTP/iTTP. Together, these approvals highlight Sanofi's*

commitment to delivering meaningful innovation and improving outcomes for people living with rare diseases in China and around the world."

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<.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 (interquartile range (IQR): 0.0–11.2) in patients without inhibitors and 1.9 (IQR: 0.0–5.6) in patients with inhibitors
- Nearly half of patients in the open-label extension study experienced one or fewer bleeds (47% 0-1 bleeds and 31% 0 bleeds)
- Nearly 80% of participants were on a regimen of six injections per year by the conclusion of the open-label extension study, and 94% achieved target AT levels with 0-1 dose adjustments

"The approval of Qfitlia marks a true transition into a new era of non-factor prophylactic treatment for hemophilia in China. Requiring potentially just six subcutaneous injections annually, it significantly reduces disease burden, eliminating the need for frequent intravenous injections associated with traditional factor therapy," said **Sun Jing**, Chief Physician of Hematology, Nanfang Hospital at Southern Medical University, Guangzhou, China. *"By lowering antithrombin to restore coagulation balance, this innovation offers people living with hemophilia A or B, with or without inhibitors, a novel treatment option."*

Serious thrombotic events, acute and recurrent gallbladder disease, and hepatotoxicity have occurred in Qfitlia-treated patients. The most common adverse reactions (incidence >10%) are viral infection, nasopharyngitis, and bacterial infection.

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 aTTP

Acquired thrombotic thrombocytopenic purpura (aTTP, also known as immune-mediated thrombotic thrombocytopenic purpura (iTTP) is an ultra-rare life-threatening autoimmune-based blood clotting disorder characterized by extensive clot formation in small blood vessels throughout the body, leading to thrombocytopenia (low platelet count); microangiopathic hemolytic anemia (loss of red blood cells through destruction); ischemia (restricted blood supply to parts of the body); and widespread organ damage, especially in the brain and heart.

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 (clinical study identifier: NCT03417102), ATLAS-A/B (clinical study identifier: NCT03417245), and ATLAS-PPX (clinical study identifier: NCT03549871). There are three ongoing phase 3 studies ATLAS-NEO (clinical study identifier: NCT05662319), ATLAS-PEDS (clinical study identifier: NCT03974113), and ATLAS OLE (clinical study identifier: 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 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 NMPA. 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.

The US Food and Drug Administration (FDA) approved Qfitlia on March 28, 2025, 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. Additional submissions for Qfitlia are under review with regulatory authorities around the world.

About Cablivi

Cablivi (caplacizumab) is a bivalent anti-von Willebrand Factor (vWF) Nanobody VHH, used in conjunction with plasma exchange and immunosuppressive therapy, for the treatment of patients experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), also known as immune-mediated thrombotic thrombocytopenic purpura (iTTP). Cablivi is the first and only treatment targeted to block the formation of microthrombi, small blood clots that form in the microvasculature, helping prevent organ damage. Cablivi is currently available in nearly 30 countries including the US, the EU, UK, Switzerland, Brazil, Colombia, Japan, and five Greater Gulf region states. Cablivi earned priority review for its approval in China, as well as priority review designation from the FDA for a pending label expansion to include the treatment of adolescents aged 12 years and older.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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