



Press Release

Sanofi's Qfitlia® (Fitusiran) receives marketing authorization in India

Approval covers both Hemophilia A and Hemophilia B with or without inhibitors — addressing a critical unmet need in India's estimated 1.4L Hemophilia population*

Mumbai, October 21, 2026: The Central Drugs Standard Control Organization (CDSCO), under the Drug Controller General of India (DCGI), has granted Marketing Authorization to Qfitlia® (Fitusiran), the first antithrombin-lowering (AT) therapy for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and adolescents (aged 12 years or older) living with hemophilia A or B, with or without factor VIII or IX inhibitors.

The approval is based on data from the ATLAS phase 3 clinical development program, which demonstrated clinically meaningful bleed-protection, as measured by annualized bleeding rates (ABR) across those living with Hemophilia with and without inhibitors.

Parwas Mahajan

Business Head, Rare Diseases, Sanofi (India)

"India carries a heavy Hemophilia burden – an estimated ~28.9k[#] registered people living with Hemophilia. Of those receiving treatment, a significant percent is still on on-demand therapy, meaning they treat bleeds only after they occur, living in constant anticipation of the next joint bleed, the next hospital visit, the next disruption to their lives and livelihoods. The approval expands prophylactic treatment options for people living with Hemophilia in India and (Prophylaxis) is increasingly recognized as an important treatment approach in the management of hemophilia, and today's approval of Qfitlia® is a significant step toward making that a reality. Our vision is a 'Hemophilia-free mind' and a life where people are not defined by their condition, where they are not held hostage by the fear of the next bleed. Qfitlia®, with its unique ability to protect both those living with Hemophilia A and Hemophilia B (with or without inhibitors) with as few as six injections a year, has the potential to significantly expand access to prophylaxis in India. Sanofi is deeply committed to India's Hemophilia community, and this approval marks the beginning of a long-term partnership with the objective of supporting improved awareness and access to appropriate hemophilia care in India."

Dr. Milan Choksey

Medical Lead, Rare Diseases Business, Sanofi India

"The approval of Qfitlia® introduces a concept that is still largely new to India: the role of antithrombin in hemostasis, and the power of lowering it to rebalance the coagulation system. For decades, our approach to Hemophilia has been to replace what is missing (factor VIII or Factor IX). Fitusiran asks a fundamentally different question: what if, instead of replacing the missing piece, we removed a brake on the system? Antithrombin is a natural inhibitor of thrombin generation. By reducing AT levels, Fitusiran allows the body's remaining coagulation machinery to work more effectively, regardless of whether the person has Hemophilia A or B, with or without inhibitors. This is the science of rebalancing and introduces a novel treatment approach that may be of interest to treating physicians. Equally important is the role of proactive AT monitoring."

The dosing of Qfitlia® is guided by AT levels – a measurable, reliable biomarker that allows physicians to personalize treatment and optimize the risk-benefit profile for each person living with Hemophilia. This is a new discipline for India, and Sanofi is committed to supporting education and appropriate implementation of AT monitoring, because the science of Fitusiran is only as powerful as the ecosystem that supports it."

About Hemophilia in India

Hemophilia A and B are rare, congenital, lifelong bleeding disorders in which the ability of a person's blood to clot is severely impaired, leading to excessive and spontaneous bleeds — particularly into joints — that can result in permanent joint damage, chronic pain, disability, and significantly reduced quality of life. Hemophilia A is caused by a deficiency of Factor VIII; Hemophilia B by a deficiency of Factor IX. In India, Hemophilia A accounts for approximately 86% of cases and Hemophilia B for 14%.

Sanofi in India

Present in India for nearly seven decades, Sanofi has earned the trust of customers and stakeholders for its commitment to promoting health. As Sanofi chases the miracles of science to improve people's lives, it continues to engage across the entire health spectrum from prevention with vaccines to wellness, treatment, patient support & capacity building.

Sanofi's India Charitable Access Program (InCAP) is the country's longest running humanitarian program providing free treatment to people afflicted with Lysosomal Storage Disorders. Sanofi conducts clinical trials in India, so that the country can have quicker access to the latest from the company's global pipeline. Sanofi India's world-class manufacturing site in Goa produces for people in India and 24+ other countries. Sanofi has located one of its Global Capability Center in Hyderabad, India, which serves as a global talent hub, providing a broad range of services across Sanofi's worldwide operations.

Sanofi (India) is a certified 'Great Place to Work' (2026-2027) and is recognized by the 'Top® Employers Institute' – a global authority that honours excellence in people practices from 2019-2024. Sanofi's local entities include Sanofi India Limited (SIL - listed entity), and Sanofi Healthcare India Pvt. Ltd. (SHIPL).

For more information, visit: www.sanofi.com/en/india, [LinkedIn](#) and [X](#).

*ICMR India ,2019

#Hemophilia Federation of India – Annual Report 2023-24

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