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Sanofiâ??s QfitliaÂ® (Fitusiran) receives marketing authorisation in India for Haemophilia treatment

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Approval covers both Hemophilia A and Haemophilia B with or without inhibitors

The Central Drugs Standard Control Organisation (CDSCO), under the Drug Controller General of India (DCGI), has granted Marketing Authorisation 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 haemophilia A or B, with or without factor VIII or IX inhibitors.

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

Parwas Mahajan, Business Head, Rare Diseases, Sanofi (India) said, "The approval expands prophylactic treatment options for people living with Haemophilia in India and (Prophylaxis) is increasingly recognised as an important treatment approach in the management of haemophilia, and today's approval of Qfitlia® is a significant step toward making that a reality. Qfitlia®, with its unique ability to protect both those living with Haemophilia 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."

Dr Milan Choksey, Medical Lead, Rare Diseases Business, Sanofi India said, "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 Haemophilia 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."