Media Update

ISTH: new data highlight innovation from Sanofi's pipeline in rare diseases

- Rilzabrutinib data cover safety and efficacy, including durable platelet response in ITP
- ALTUVIIIO and Qfitlia data reinforce Sanofi as a leader in hemophilia committed to providing more treatment options

Paris, June 6, 2025. New data from 18 abstracts, including five oral presentations, will be presented at the 33rd congress of the International Society on Thrombosis and Haemostasis (ISTH) in Washington D.C., US from June 21 to 25, 2025, highlighting Sanofi as a leader in hemophilia committed to rare blood diseases. Data to be presented expand on the potential of rilzabrutinib to address the underlying immune dysregulation of immune thrombocytopenia (ITP) and strengthen Sanofi as a leader in hemophilia with ALTUVIIIO and the newly launched Qfitlia, aimed at providing more treatment options to help improve patients' lives.

> ***Christopher Corsico, MD***
> Global Head of Development
> *"Our commitment to rare blood diseases drives us to find innovative solutions for the persistent unmet needs of patients and caregivers. Our data highlight the benefits of our hemophilia treatments and the potential of our reversible oral BTK inhibitor, rilzabrutinib, which could be transformative in rare diseases marked by complex immune dysregulation and inflammation."*

Rilzabrutinib targets the underlying immune dysregulation in ITP

New findings from the LUNA 3 phase 3 study of rilzabrutinib in ITP will be included in an oral presentation highlighting platelet response as defined by International Working Group (IWG) criteria – a clinically meaningful endpoint used to guide treatment decisions. Two additional poster presentations will detail the first efficacy and safety report from the LUNA 3 open-label period, along with new insights into platelet count variability in patients treated with rilzabrutinib.

The safety and efficacy of rilzabrutinib have not been determined by any regulatory authority. Rilzabrutinib is currently under regulatory review in the US, the EU, and China in ITP. The target action date for the US Food and Drug Administration regulatory decision for ITP, which was granted fast track designation, is August 29, 2025. Rilzabrutinib has received orphan drug designation in various parts of the world in several potential indications, including ITP, wAIHA, sickle cell disease, and IgG4-related disease.

Qfitlia modeling data predict correlation between lowering AT levels and bleed protection

Two oral presentations will feature data from the ATLAS clinical development program for Qfitlia, using modeling approaches to predict the correlation between AT levels and annualized bleeding rates for patients treated prophylactically with Qfitlia, the first antithrombin (AT)-lowering therapy in hemophilia.

Long-term extension data reinforce ALTUVIIIO efficacy as leading treatment for hemophilia A

Additional analysis from the long-term XTEND-ed phase 3 study supports the efficacy and safety profiles of ALTUVIIIO in adult and pediatric patients with severe hemophilia A. Data support ALTUVIIIO benefits in treating bleeding episodes in children regardless of bleed type and location. Moreover, the XTEND clinical program continued to assess the outcomes with ALTUVIIIO in the perioperative management of major and minor surgeries in adults and children with severe hemophilia A.

Complete list of ISTH 2025 presentations:

Presenting author	Abstract title	Presentation details
ITP		
Ghanima	Platelet responses per IWG criteria for LUNA3 rilzabrutinib vs placebo in primary ITP patients	25-June-2025 Oral presentation: 10:15am-11:30am ET
Kuter	LUNA3 open-label period: first efficacy/safety with rilzabrutinib in previously treated ITP adults	22-June-2025 Poster #PB0376 presentation: 1:45pm-2:45pm ET
Arnold	Effect of rilzabrutinib on platelet count variability in previously treated ITP: LUNA3 phase 3 data	22-June-2025 Poster #PB03555 presentation: 1:45pm-2:45pm ET
Hemophilia A and B (fitusiran)		
Young	Association of antithrombin levels with efficacy of fitusiran prophylaxis in people with hemophilia A or B, with and without inhibitors: a predictive modeling approach	24-June-2025 Oral presentation: 3:15pm-3:30pm ET
Pipe	Pharmacodynamics and pharmacokinetics of fitusiran antithrombin-based dose regimen (AT-DR): clinical and population modeling data	24-June-2025 Oral presentation: 2:45pm-3:00pm ET
Chowdary	Low incidence of anti-drug antibodies to fitusiran in people with hemophilia A or B, with or without inhibitors	23-June-2025 Poster #PB0844 presentation: 1:45pm-2:45pm ET
Freidel	Antithrombin activity measurement via the INNOVANCE antithrombin assay* to manage fitusiran dosing (* Siemens Healthineers collaboration)	23-June-2025 Poster #PB0784 presentation: 1:45pm-2:45pm ET
Hemophilia A (efanesoctocog alfa)		
Malec	Treatment of bleeding episodes with efanesoctocog alfa in children: XTEND-ed second interim analysis	22-June-2025 Oral presentation: 3:45pm-4:00pm ET
Khoo	Major surgical outcomes with efanesoctocog alfa: 4 years' experience in the XTEND clinical program	24-June-2025 Oral presentation: 3:30pm-3:45pm ET
Königs	Joint health outcomes with efanesoctocog alfa in adults/adolescents from XTEND-1 continuing XTEND-ed	24-June-2025 Poster #PB1425 presentation: 1:45pm-2:45pm ET
Roberts	Long-term observational joint health study in patients initiating efanesoctocog alfa: baseline data	24-June-2025 Poster #PB1434presentation: 1:45pm-2:45pm ET
Weng	Observational study of prophylactic efanesoctocog alfa for joint health in hemophilia A: PROTECT-ALT	24-June-2025 Poster #PB1441 presentation: 1:45pm-2:45pm ET
Chowdary	Minor surgeries outcomes with efanesoctocog alfa: 4 years' experience in the XTEND clinical program	23-June-2025 Poster #PB0847 presentation: 1:45pm-2:45pm ET
Hemophilia B (recombinant factor IX Fc)		
Glosli	Real-world effectiveness and usage of Recombinant Factor IX Fc: Final data from the B-MORE study (Sobi collaboration)	23-June-2025 Poster #PB0868 Presentation: 1:45pm-2:45pm ET
Hermans	Extravascular distribution of factor IX: evidence and relevance for hemophilia B replacement therapy (Sobi collaboration)	23-June-2025 Poster #PB0816 Presentation: 1:45pm-2:45pm ET

Iorio	Association between FIX levels & bleeding rates in hemophilia B patients receiving rFIXFc or N9-GP	23-June-2025 Poster #PB0788 Presentation: 1:45pm-2:45pm ET
Hemophilia		
Álvarez Román	Monitoring joint health of patients with hemophilia in Spain. Updated analysis of the JOINt US project (Sobi collaboration)	24-June-2025 Poster #PB1439 Presentation: 1:45pm-2:45pm ET
Hermans	Unmet medical needs and health inequities in people with hemophilia A: development of expert consensus statements (Sobi collaboration)	23-June-2025 Poster #PB0778 Presentation: 1:45pm-2:45pm ET

About rilzabrutinib

Rilzabrutinib is a novel, advanced, oral, reversible Bruton's tyrosine kinase (BTK) inhibitor that has the potential to be an effective new medicine for several rare immune-mediated or inflammatory diseases by working to restore immune balance via multi-immune modulation. BTK, expressed in B cells, macrophages, and other innate immune cells, plays a critical role in multiple immune-mediated disease processes and inflammatory pathways. With the application of Sanofi's TAILORED COVALENCY® technology, rilzabrutinib can selectively inhibit the BTK target while potentially reducing the risk of off-target side effects.

About Qfitlia

Qfitlia (fitusiran) is a first-in-class antithrombin (AT) lowering therapy approved in the US and the United Arab Emirates for prophylactic treatment of adults and pediatric patients (aged 12 and older) living with hemophilia A or 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 ALTUVIIIO

ALTUVIIIO (recombinant antihemophilic factor, Fc-VWF-XTEN fusion protein) is a first-in-class high-sustained factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for adults and children with hemophilia A. In adults and adolescents, ALTUVIIIO has a three to four-fold longer half-life relative to standard and extended half-life factor VIII products, providing high-sustained factor activity levels within normal to near-normal range, allowing for once-weekly administration. ALTUVIIIO is the first factor VIII therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on earlier generation factor VIII therapies. ALTUVIIIO builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to extend its time in circulation. ALTUVIIIO is currently approved and marketed in the US (granted priority review), Japan, and Taiwan. On June 17, 2024, it was approved by the European Commission for the treatment and prevention of bleeds and perioperative prophylaxis in hemophilia A under the name Altuvoct®.

ALTUVIIIO is the first factor VIII therapy to receive breakthrough therapy designation in the US and China, US fast track designation, and orphan drug designation in the US and EU.

About the Sanofi and Sobi collaboration

Sobi and Sanofi collaborate on the development and commercialization of Alprolix and Elocta/Eloctate. The companies also collaborate on the development and commercialization of efanesoctocog alfa, or ALTUVIIIO in the US, Japan, and Taiwan, and Altuvoct in Europe. Sobi has final development and commercialization rights in the Sobi territory (essentially Europe, North Africa, Russia, and most Middle Eastern markets). Sanofi has final development and commercialization rights in North America and all other regions in the world excluding the Sobi territory.

About Sobi

Sobi® is a global biopharma company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,800 employees across Europe, North America, the Middle East, Asia and Australia. In 2024, revenue amounted to SEK 26 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn.

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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Sanofi forward-looking statements

This media update contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions, and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.