Press Release

Sanofi's Wayrilz recommended for EU approval by the CHMP to treat immune thrombocytopenia

- Recommendation based on LUNA 3 phase 3 study demonstrating rapid and durable platelet response and significant improvements in bleeding, quality of life measures, and other ITP symptoms
- If approved, Wayrilz will be the first BTK inhibitor for ITP in the EU, targeting the root cause of the disease through multi-immune modulation

Paris, October 17, 2025. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Wayrilz (rilzabrutinib) as a new treatment for immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. A final decision is expected in the coming months.

> *"The CHMP's recommendation of Wayrilz for approval is a positive step forward for people in the EU living with ITP who continue to experience symptoms that impact their daily living despite treatment with certain other therapies," said* **Brian Foard**, Executive Vice President, Head of Specialty Care at Sanofi. *"Through multi-immune modulation, Wayrilz shows promise in addressing the root cause of ITP – complex immune system dysregulation, reinforcing Sanofi's commitment to finding novel ways to address unmet patient needs in rare and immunological diseases."*

The positive CHMP opinion is based on the pivotal LUNA 3 phase 3 study (clinical study identifier: NCT04562766), presented at the 66th American Society of Hematology Annual Meeting and Exposition in December 2024 and also published in *Blood.* Wayrilz met both the primary and secondary endpoints, making LUNA 3 the first phase 3 study to show a positive impact on sustained platelet counts, bleeding, and other ITP symptoms with an oral, reversible, Bruton's tyrosine kinase (BTK) inhibitor.

Wayrilz has already been approved in the US and the United Arab Emirates. In addition to the EU, Wayrilz is currently under regulatory review for ITP in China. It received fast track and orphan drug designations (ODD) in the US for ITP, with similar orphan designations in the EU and Japan. In other indications under investigation, the US Food and Drug Administration (FDA) granted Wayrilz ODD for three additional rare diseases, including warm autoimmune hemolytic anemia (wAIHA), IgG4-related disease (IgG4-RD), and sickle cell disease (SCD). Wayrilz also received FDA fast track designation and EU orphan designation in IgG4-RD.

About the LUNA 3 study

LUNA 3 (clinical study identifier: NCT04562766) was a randomized, multicenter, phase 3 study evaluating the efficacy and safety of Wayrilz vs. placebo in adult and adolescent patients with persistent or chronic ITP. Patients received either oral Wayrilz 400 mg twice a day or placebo through a 12- to 24-week double-blind treatment period, followed by a 28-week open-label treatment period, and then a four-week safety follow-up or long-term extension period. The adolescent part of the study is ongoing. The primary endpoint for the EU is the proportion of adult participants able to achieve platelet counts at or above 50,000/µL for at least eight out of the last 12 weeks of the 24-week blinded treatment period in the absence of rescue therapy. Secondary endpoints included time to platelet response (platelet count ≥50 x 10^9/L or between 30 x 10^9/L and <50 x 10^9/L and at least doubled from baseline in absence of rescue therapy), number of weeks maintaining a specific platelet response (i.e., doubled or within range), rescue therapy use, physical fatigue score, and bleeding score as assessed by change from baseline in Idiopathic Thrombocytopenic Purpura Bleeding Scale (IBLS) assessment at Week 25.

About Wayrilz

Wayrilz (rilzabrutinib) is the first BTK inhibitor for ITP that helps address the root cause of disease through multi-immune modulation. This innovative therapy is approved in the US for adults with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. Additionally, Wayrilz is approved in the United Arab Emirates for adult patients with persistent or chronic ITP who have had an insufficient response or intolerance to a previous treatment. 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, Wayrilz can selectively inhibit the BTK target.

Wayrilz is being studied across a variety of rare diseases, including wAIHA, IgG4-RD, and SCD. These additional indications are currently under investigation and have not been approved by regulatory authorities.

About ITP

ITP is a disease of complex immune dysregulation that causes low platelet counts (<100,000/µL), resulting in a variety of bleeding symptoms and thromboembolism risk. Beyond bruising and bleeding, which can include potentially life-threatening episodes like intracranial hemorrhage, people living with ITP may experience reduced quality of life, including physical fatigue and cognitive impairment.

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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