Press Release

Sanofi's Wayrilz approved in the EU as the first BTK inhibitor to treat immune thrombocytopenia

- Novel treatment targets BTK through multi-immune modulation to help address the underlying causes of ITP
- Approval based on the LUNA 3 phase 3 study that demonstrated rapid and durable platelet response and improvements in other ITP symptoms
- ITP is a rare disease of complex immune dysregulation leading to lower platelet counts, bleeding, and reduced quality of life

Paris, December 23, 2025 – The European Commission has approved Wayrilz (rilzabrutinib), a novel, oral, reversible, Bruton's tyrosine kinase (BTK) inhibitor, as a new treatment for immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. This follows the positive opinion by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP).

Wayrilz can help address the underlying causes of ITP through multi-immune modulation, targeting different pathways across the immune system.

> *"ITP is caused by complex immune system dysregulation leading to low platelet counts, bleeding and other often overlooked symptoms that can affect both physical and mental health, significantly impacting quality of life,"* said **Waleed Ghanima, MD**, Head of Research and a Consultant Hematologist at Østfold Hospital, Norway. *"The traditional approach to disease management focuses on restoring platelet counts and reducing bleeding risk, but patients may still experience other symptoms. Wayrilz offers a new approach, targeting the underlying cause of ITP through multi-immune modulation to help address the multi-faceted burden of this disease."*
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> *"The approval of Wayrilz in the EU for the treatment of ITP underscores Sanofi's commitment to leveraging our knowledge of the immune system to develop innovative treatments that make a meaningful impact on people living with rare and inflammatory diseases,"* said **Brian Foard**, Executive Vice President, Head of Specialty Care at Sanofi. *"Wayrilz has a differentiated mechanism of action, enabling multi-immune modulation to address the underlying pathology of ITP, allowing patients to benefit from an advanced treatment to help manage their disease."*

The EU approval of Wayrilz is based on the pivotal LUNA 3 phase 3 study (clinical study identifier: NCT04562766), in which Wayrilz met the primary and secondary endpoints, demonstrating a positive impact on sustained platelet counts as well as other ITP symptoms.

The LUNA 3 phase 3 study, presented at the 66th American Society of Hematology Annual Meeting and Exposition, and also published in *Blood*, evaluated the efficacy and safety of Wayrilz compared to placebo in adults (n=202) with persistent or chronic ITP. Patients who achieved platelet count response at 12 weeks were eligible to continue the full 24-week double-blind period (64% of patients in the Wayrilz arm and 32% of patients in the placebo arm). Patients receiving Wayrilz experienced the following compared to patients receiving placebo:

- Statistically significant durable platelet response at week 25 (23% of patients in Wayrilz arm vs. 0% in placebo arm; $p<0.0001$)
- Faster time to first platelet response (36 days in Wayrilz arm vs. not reached in placebo arm; $p<0.0001$)
- Longer duration of platelet response (least square mean of 7 weeks in Wayrilz arm vs. 0.7 weeks in placebo arm)

Patients receiving Wayrilz reported an overall 10.6-point improvement in the overall quality of life domain compared to a 2.3-point increase in the placebo arm, based on The Immune Thrombocytopenia Patient Assessment Questionnaire, a clinical tool designed to measure ITP symptoms and impacts. The results of this analysis are descriptive and were not powered for statistical significance.

The most common adverse reactions (incidence ≥10%) are diarrhea, nausea, headache, abdominal pain, and COVID-19.

Wayrilz has already been approved in the US and the United Arab Emirates (UAE), and it is currently under regulatory review for ITP in Japan and 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. 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. This innovative therapy is now approved for ITP in the US, in the EU, and in the UAE. Regulatory review for use in ITP is currently ongoing in China and Japan.

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 high risk of 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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