

# Sanofi's Wayrilz approved in Japan to treat immune thrombocytopenia

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

**Paris, June 23, 2026.** The Ministry of Health, Labour and Welfare in Japan has granted marketing and manufacturing authorization to Wayrilz (rilzabrutinib), a novel oral reversible Bruton's tyrosine kinase inhibitor (BTKi), for the treatment of persistent or chronic immune thrombocytopenia (ITP) in patients who do not respond sufficiently to other treatments or in whom tolerability is considered to be problematic. Wayrilz can help address the underlying causes of the disease, through multi-immune modulation, targeting key pathways across the immune system.

The approval is based on the LUNA 3 phase 3 study (clinical study identifier: [NCT04562766](#)), in which Wayrilz met the primary and secondary endpoints, showing a positive impact on sustained platelet counts and other symptoms.

*"For ITP patients, achieving platelet counts close to normal and living without worrying about bleeding is extremely important. Additionally, in recent years, there has been growing interest in various other symptoms associated with ITP such as fatigue,"* said **Hisashi Kato**, MD, PhD, Department of Blood Transfusion and Cell Therapy, The University of Osaka Hospital, Suita, Japan. *"Wayrilz is a novel BTKi that works through multi-immune modulation to help address the root cause of ITP pathophysiology. It is expected to become a new therapeutic option that may help patients with disease management, including not only improvement in platelet counts but also considering patients' quality of life."*

*"People living with immune thrombocytopenia who continue to experience symptoms, despite trying existing treatments, face a great unmet need,"* said **Manuela Buxo**, Executive Vice President, Global Head of Specialty Care at Sanofi. *"Wayrilz has a differentiated mechanism of action that enables multi-immune modulation to address the underlying pathophysiology of ITP and offers new hope to patients who have not responded to prior therapy. This milestone underscores Sanofi's commitment to bringing innovative treatment options to rare disease patients around the world."*

The LUNA 3 phase 3 study 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  $\geq 10\%$ ) were diarrhea, nausea, headache, abdominal pain, and COVID-19.

Wayrilz is being studied across multiple other rare diseases, including IgG4-related disease (IgG4-RD), warm autoimmune hemolytic anemia (wAIHA), and sickle cell disease. These additional indications are currently under investigation and have not been approved by regulatory authorities. Japan has granted Wayrilz orphan drug designation for ITP, IgG4-RD, and wAIHA.

### **About ITP**

ITP is a disease of complex immune dysregulation that causes low platelet counts ( $< 100,000/\mu\text{L}$ ), resulting in a variety of bleeding symptoms and high risk of thromboembolism. 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 Wayrilz**

Wayrilz (rilzabrutinib) is a novel oral reversible covalent 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. The enzyme 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 the TAILORED COVALENCY<sup>®</sup> technology, Wayrilz can selectively inhibit the BTK target. Wayrilz is now approved for the treatment of ITP in the US, the EU, the UAE, the UK and Japan.

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### *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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