16 October 2025
EMA/CHMP/228349/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Wayrilz

rilzabrutinib

On 16 October 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Wayrilz[2], intended for the treatment of immune thrombocytopenia (ITP) in adults who are refractory to other treatments.

The applicant for this medicinal product is Sanofi B.V.

Wayrilz will be available as 400 mg film-coated tablets. The active substance of Wayrilz is rilzabrutinib, a Bruton's tyrosine kinase (BTK) inhibitor (ATC code: not yet assigned). Rilzabrutinib mediates its therapeutic effect through multi-immune modulation by inhibiting B cell activation, interrupting FcγR mediated phagocytosis, and potentially ameliorating chronic inflammation associated with ITP.

The benefits of Wayrilz include a significantly higher rate of durable platelet response in adults with ITP refractory to other treatments compared with placebo, especially when used in combination with corticosteroids and/or thrombopoietin receptor agonists, as shown in a phase 3 multicentre, randomised, double-blind, placebo-controlled study. The most common side effects with Wayrilz include diarrhoea, nausea, headache, COVID-19, abdominal pain, arthralgia and nasopharyngitis.

The full indication is:

> WAYRILZ is indicated for the treatment of immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.

Treatment with Wayrilz should be initiated and remain under the supervision of physicians experienced in the treatment of haematological diseases.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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