23 April 2026
EMADOC-1829012207-47809
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cenrifki

tolebrutinib

On 23 April 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cenrifki, intended for the treatment of multiple sclerosis.

The applicant for this medicinal product is Sanofi Winthrop Industrie.

Cenrifki will be available as 60 mg film-coated tablets. The active substance of Cenrifki is tolebrutinib, a selective immunosuppressant (ATC code: L04AA62). Tolebrutinib is an inhibitor of Bruton's tyrosine kinase. The exact mechanism by which tolebrutinib exerts its therapeutic effect in multiple sclerosis is not fully understood and it is considered that it inhibits the activation of B cells, macrophages and microglia in the periphery and central nervous system.

The benefits of Cenrifki are a 31% reduction in the risk of 6-month confirmed disability progression and a 38% reduction in the adjusted mean number of new and/or enlarging T2-hyperintense lesions per year compared with patients given placebo.

The most common side effects with Cenrifki are infections, petechiae, increased tendency to bruise, heavy menstrual bleeding, abdominal pain, contusion and increased levels of liver enzymes. The most worrisome side effect is the drug-induced liver injury.

The full indication is:

> Cenrifki is indicated for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) without relapses in the last 2 years (see section 5.1).

Cenrifki should be prescribed by physicians experienced in the treatment of multiple sclerosis.

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

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