24 July 2025
EMA/214551/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Romvimza

vimseltinib

On 24 July 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 Romvimza[2], intended for the treatment of adults with symptomatic tenosynovial giant cell tumour (TGCT). The applicant for this medicinal product is Deciphera Pharmaceuticals (Netherlands) B.V.

Romvimza will be available as 14 mg, 20 mg and 30 mg hard capsules. The active substance of Romvimza is vimseltinib, an antineoplastic agent, protein kinase inhibitor (ATC code: L01EX29) that targets colony stimulating factor 1 receptor (CSF1R). The CSF1/CSF1R signalling axis has a critical role in the development of TGCT. Vimseltinib exerts its antineoplastic activity by inhibiting CSFR1 expressing cells and blocking downstream signalling pathways that promote tumour growth and macrophage proliferation.

The benefit of Romvimza is based on an improved overall response rate (ORR) at week 25 in adults with symptomatic TGCT compared with placebo in a multicentre, randomised phase 3 study with an open-label extension phase. At week 97 a high rate of complete response was observed.

The most common side effects with Romvimza include increased aspartate aminotransferase (AST), periorbital oedema, increased cholesterol, rash, increased creatinine, decreased neutrophils, fatigue, face oedema, increased alanine aminotransferase (ALT), pruritus, peripheral oedema and hypertension.

The full indication is:

> ROMVIMZA is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability.

Romvimza should be initiated by a healthcare professional experienced in the diagnosis and treatment of TGCT.

Detailed recommendations for the use of this product will be described in the summary of product

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.