EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2026
EMA/CHMP/43372/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ojemda

tovorafenib

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Ojemda[3], intended for the treatment of paediatric low-grade glioma (LGG) with *BRAF* alterations, in patients aged 6 months and older whose disease has progressed after one or more prior systemic therapies.

The applicant for this medicinal product is Ipsen Pharma.

Ojemda will be available as a 25 mg/ml powder for oral suspension and as 100 mg film-coated tablets. The active substance of Ojemda is tovorafenib, a b-RAF serine-threonine kinase (BRAF) inhibitor (ATC code: L01EC04). Tovorafenib works by blocking RAF proteins involved in tumour growth. By targeting these proteins, tovorafenib helps to slow down or stop the signals that cause tumour cells with certain *BRAF* alterations (including *BRAF* V600 mutations and *BRAF* fusions) to grow and multiply.

The benefits of Ojemda are a 52.6% (95% CI: 40.8, 64.2) overall response rate and a median duration of response of 18.0 months (95% CI: 12.0, 22.8) in patients with paediatric LGG harbouring a *BRAF* fusion or rearrangement or *BRAF* V600 mutation, whose disease has progressed after one or more prior systemic therapies, as observed in a phase 2, open-label, single-arm clinical study involving 77 patients.

The most common side effects include hair colour changes, hypophosphataemia, headache, rash maculo-papular, pyrexia, growth retardation, dry skin aspartate aminotransferase increased, blood lactate dehydrogenase increased and nausea.

The full indication is:

> Ojemda is indicated as monotherapy for the treatment of patients 6 months of age and older with paediatric low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement, or BRAF

[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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.
[3] 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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V600 mutation, who have progressed after one or more prior systemic therapies.

Treatment with Ojemda should be initiated and supervised by a qualified physician experienced in the use of anti-cancer medicinal products.

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.