19 June 2025
EMA/124078/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ogsiveo

nirogacestat

On 19 June 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 Ogsiveo[2], intended for the treatment of adults with progressing desmoid tumours. The applicant for this medicinal product is SpringWorks Therapeutics Ireland Limited.

Ogsiveo will be available as 50 mg, 100 mg and 150 mg film-coated tablets. The active substance of Ogsiveo is nirogacestat, an antineoplastic agent (ATC code: L01XX81). Nirogacestat is an inhibitor of gamma secretase. By blocking gamma secretase, it inhibits the Notch signalling pathway, thereby preventing tumour growth.

The benefit of Ogsiveo is a statistically significant improvement in progression-free survival (PFS) compared with placebo, as observed in an international, multicentre, randomised, double-blind, placebo-controlled phase 3 study in adults with progressing desmoid tumours.

The most common side effects with Ogsiveo are diarrhoea, rash, ovarian toxicity in women of childbearing potential, nausea, fatigue, hypophosphataemia, headache, and stomatitis.

The full indication is:

> Ogsiveo as monotherapy is indicated for the treatment of adult patients with progressing desmoid tumours who require systemic treatment.

Ogsiveo should be initiated and monitored by physicians experienced in the use of anticancer therapies.

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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