17 September 2026
EMA/CHMP/205829/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Gevalka

ensartinib

On 17 September 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 Gevalka, intended for the treatment of adults with anaplastic lymphoma kinase (ALK)-positive, advanced non-small cell lung cancer (NSCLC).

The applicant for this medicinal product is SFL Pharmaceuticals Deutschland GmbH.

Gevalka will be available as 25 mg and 100 mg capsules. The active substance of Gevalka is ensartinib, a protein kinase inhibitor (ATC code: not yet assigned). Ensartinib inhibits the phosphorylation of ALK and its downstream signalling, thereby preventing the proliferation of ALK-dependent cancer cells.

The benefit of Gevalka in the first-line setting is an improvement in progression free survival in patients taking ensartinib compared with patients taking crizotinib, as observed in an open-label, randomised, active-controlled, multicentre study in adults with ALK-positive NSCLC that was either locally advanced (stage IIIB following prior chemotherapy or chemoradiation or not candidates for curative-intent therapy) or metastatic. Gevalka has also shown clinically relevant response rates in adults with ALK-positive NSCLC previously treated with crizotinib.

The most common side effects with Gevalka are rash, liver function test abnormalities, pruritus and nausea.

The full indication is:

> Gevalka is indicated as monotherapy:
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> - for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.
> - for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib.
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> For biomarker-based patient selection, see section 4.2.

[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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Treatment with Gevalka should be initiated and supervised by a physician experienced in the use of anticancer 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.