11 December 2025
EMA/CHMP/369595/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Aumseqa

aumolertinib

On 11 December 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 Aumseqa, intended for the treatment of non-small cell lung cancer (NSCLC).

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

Aumseqa will be available as 55 mg film-coated tablets. The active substance of Aumseqa is aumolertinib, an EGFR tyrosine kinase inhibitor (ATC code: L01EB11). Aumseqa irreversibly inhibits EGFR with the sensitising mutations EGFR exon 19 deletion (Ex19Del) and L858R, and EGFR resistance mutation (EGFR T790M).

The benefits of Aumseqa are an improvement in progression-free survival (PFS) compared with gefitinib monotherapy in patients with advanced NSCLC harbouring an EGFR exon 19 deletion or L858R mutation and its objective response rate and duration of response in patients with advanced NSCLC harbouring the EGFR T790M mutation. The most common side effects with Aumseqa are aspartate aminotransferase (AST) increased, hyponatraemia, alanine aminotransferase (ALT) increased, blood CPK increased, white blood cell count decreased, platelet count decreased, upper respiratory tract infections and rash.

The full indication is:

> Aumseqa as monotherapy is indicated for:
>
> - the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations (for biomarker-based patient selection, see section 4.2).
> - the treatment of adult patients with advanced EGFR T790M mutation-positive NSCLC (for biomarker-based patient selection, see section 4.2).

Treatment with Aumseqa should be initiated by a physician experienced in the use of anticancer medicinal products.

[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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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.