



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2021
EMA/CHMP/684399/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Lorviqua

lorlatinib

On 16 December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Lorviqua. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted a new indication as follows:²

Lorviqua as monotherapy is indicated 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.

Lorviqua as monotherapy is indicated for the treatment of adult patients with ALK positive advanced NSCLC whose disease has progressed after:

- alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or
- crizotinib and at least one other ALK TKI.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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 New text in bold

