25 April 2024
EMA/CHMP/164804/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Alecensa

alectinib

On 25 April 2024, 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 Alecensa. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted a new indication as follows:

> Adjuvant treatment of resected non-small cell lung cancer (NSCLC)
>
> Alecensa as monotherapy is indicated as adjuvant treatment following complete tumour resection for adult patients with ALK-positive NSCLC at high risk of recurrence (see section 5.1 for selection criteria).

For information, the full indications for Alecensa will be as follows[2]:

> **Adjuvant treatment of resected non-small cell lung cancer (NSCLC)**
>
> **Alecensa as monotherapy is indicated as adjuvant treatment following complete tumour resection for adult patients with ALK-positive NSCLC at high risk of recurrence (see section 5.1 for selection criteria).**
>
> Treatment of advanced NSCLC
>
> Alecensa as monotherapy is indicated for the first-line treatment of adult patients with ALK-positive advanced NSCLC.
>
> Alecensa as monotherapy is indicated for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib.

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 made available in all official European Union languages after a decision on this change to the

[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

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marketing authorisation has been granted by the European Commission.