EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2017
EMA/CHMP/660204/2017
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Alecensa

alectinib

On 12 October 2017, 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 Limited.

The CHMP adopted an extension to the existing indication as follows[2]:

> "**Alecensa as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).**
>
> Alecensa as monotherapy is indicated for the treatment of adult patients with ~~anaplastic lymphoma kinase (~~ALK~~)~~-positive advanced ~~non-small cell lung cancer (~~NSCLC~~)~~ previously treated with crizotinib".

In addition, since all specific obligations of the conditional marketing authorisation have been fulfilled, the marketing authorisation for Alecensa will be switched from conditional to full approval.

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, removed text as strikethrough

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