21 July 2016
EMA/CHMP/488316/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xalkori

crizotinib

On 21 July 2016, 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 Xalkori. The marketing authorisation holder for this medicinal product is Pfizer Limited.

The CHMP adopted a new indication as follows:

> "Xalkori is indicated for the treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC)."

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

> "Xalkori is indicated for the first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).
>
> Xalkori is indicated for the treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).
>
> **Xalkori is indicated for the treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC).**"

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

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