27 June 2024
EMA/CHMP/293420/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xalkori

crizotinib

On 27 June 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 Xalkori. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted an extension to existing indications [anaplastic lymphoma kinase (ALK)-positive anaplastic large cell lymphoma (ALCL) and unresectable inflammatory myofibroblastic tumour (IMT)] in to include treatment of children from 1 year of age. For information, the full indication will be as follows:[2]

Xalkori as monotherapy is indicated for:

- The first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)
- The treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)
- The treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC)
- The treatment of paediatric patients (age ≥**1**~~6~~ to <18 years) with relapsed or refractory systemic anaplastic lymphoma kinase (ALK)-positive anaplastic large cell lymphoma (ALCL)
- The treatment of paediatric patients (age ≥**1**~~6~~ to <18 years) with recurrent or refractory anaplastic lymphoma kinase (ALK)-positive unresectable inflammatory myofibroblastic tumour (IMT)

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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