19 July 2012
EMA/CHMP/453868/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xalkori

crizotinib

On 19 July 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Xalkori, 200 mg, 250 mg, hard capsule intended for the treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). The applicant for this medicinal product is Pfizer Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Xalkori is crizotinib, a protein kinase inhibitor (L01XE16) the antineoplastic activity of which is linked to the selective inhibition of the ALK receptor tyrosine kinase (RTK) and its oncogenic variants (i.e. ALK fusion events and selected ALK mutations). Xalkori is also an inhibitor of the Hepatocyte Growth Factor Receptor (HGFR, c-Met) RTK.

The benefits with Xalkori are its important activity on ALK-positive NSCLC with an objective response rate of 60% (95% CI, 51% - 69%) and a median progression free survival (PFS) of 9.2 months (95% CI, 7.3 months – 12.7 months). The most common side effects are vision disorder, nausea, diarrhoea, vomiting, oedema, constipation, and fatigue. The potentially serious adverse reactions are hepatotoxicity, pneumonitis and QT interval prolongation

A pharmacovigilance plan for Xalkori will be implemented as part of the marketing authorisation.

The approved indication is: "XALKORI is indicated for the treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)". It is proposed that Xalkori be initiated and supervised by a physician experienced in the use of anticancer medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[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.

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Xalkori and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.