15 December 2016
EMA/858904/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Alecensa

alectinib

On 15 December 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Alecensa, intended for the treatment of patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib. The applicant for this medicinal product is Roche Registration Limited.

Alecensa will be available as 150 mg hard capsules. The active substance of Alecensa is alectinib, a protein kinase inhibitor (L01XE36) that inhibits autophosphorylation of ALK, ALK-mediated phosphorylation of downstream signalling proteins and proliferation of ALK-dependent cancer cells.

The benefits with Alecensa are its important activity on ALK-positive NSCLC in patients previously treated with crizotinib, with objective response rates of 50.8% and 52.2% (response evaluable population) in two phase II studies. The median duration of response in the studies was 15.2 and 14.9 months, respectively and the median progression free survival was 8.9 and 8.2 months.

The most common side effects are constipation, oedema (including peripheral oedema, generalised oedema, eyelid oedema, periorbital oedema), myalgia (including myalgia and musculoskeletal pain) and nausea. The most serious adverse reactions are interstitial lung disease/pneumonitis, hepatotoxicity, severe myalgia and creatine phosphokinase (CPK) elevation and bradycardia.

The full indication is: "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". It is proposed that Alecensa be prescribed by physicians 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 made available in all official European Union languages after the marketing authorisation has been

[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] 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.

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