

26 February 2015
EMA/140022/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Zykadia ceritinib

On 26 February 2015 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 Zykadia, 150 mg, hard capsule, intended for the treatment of adult 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 Novartis Europharm 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 Zykadia is ceritinib, a protein kinase inhibitor (L01XE28), inhibiting autophosphorylation of ALK, ALK mediated phosphorylation of downstream signalling proteins and proliferation of ALK dependent cancer cells.

The benefits with Zykadia are its important activity on ALK-positive NSCLC in patients previously treated with crizotinib, with an objective response rate of 56.4 % and 37.1% in a phase I and II study, respectively. The median duration of response was 8.3 and 9.2 months, respectively. The most common side effects are diarrhoea, nausea, vomiting, fatigue, liver laboratory test abnormalities, abdominal pain, decreased appetite, constipation, rash, blood creatinine increased, oesophageal disorder and anaemia. The most serious adverse reactions are hepatotoxicity, gastrointestinal effects, QT interval prolongation, bradycardia, interstitial lung disease/pneumonitis and hyperglycaemia.

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

The approved indication is: "Zykadia 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 Zykadia be prescribed by physicians experienced in the treatment of anti-cancer 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.



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 Zykadia and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional².

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.