17 December 2015
EMA/776644/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tagrisso

osimertinib

On 17 December 2015 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 Tagrisso, intended for the treatment of locally advanced or metastatic non-small-cell lung cancer (NSCLC) associated with a particular genetic mutation (T790M). The applicant for this medicinal product is AstraZeneca AB.

Tagrisso will be available as 40 mg and 80 mg film-coated tablets. The active substance of Tagrisso is osimertinib, a tyrosine kinase inhibitor (ATC code: L01XE35). Osimertinib is an irreversible inhibitor of epidermal growth factor receptors that harbour sensitising mutations (EGFRm) and TKI-resistance mutation T790M.

The benefits with Tagrisso are its significant activity in patients with NSCLC harbouring the T790M mutation. The most common side effects are diarrhoea and rash. The most common severe side effects are pneumonia, pulmonary embolism and dyspnoea.

The full indication is: "Tagrisso is indicated for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC)." It is proposed that Tagrisso should be initiated by a physician experienced in the use of anticancer therapies.

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 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] 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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