



26 April 2018
EMA/CHMP/254059/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tagrisso

osimertinib

On 26 April 2018, 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 Tagrisso. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted an extension to the existing indication as follows²:

“Tagrisso **as monotherapy** is indicated for:

- **the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.**
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.”

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

