EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2018
EMA/489607/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Gefitinib Mylan

gefitinib

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Gefitinib Mylan, intended for the treatment of non-small cell lung cancer (NSCLC). The applicant for this medicinal product is MYLAN S.A.S.

Gefitinib Mylan will be available as 250-mg film-coated tablet. The active substance of Gefitinib Mylan is gefitinib, an anti-neoplastic medicinal product (ATC code: L01XX31) which targets the epidermal growth factor receptor (EGFR) tyrosine kinase and acts as an inhibitor of cell growth by competing with ATP and blocking activation through the receptor.

Gefitinib Mylan is a generic of Iressa, which has been authorised in the EU since 24 June 2009. Studies have demonstrated the satisfactory quality of Gefitinib Mylan, and its bioequivalence to the reference product Iressa. A question and answer document on generic medicines can be found here.

The full indication is:

"Gefitinib Mylan is indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR TK."

It is proposed that Gefitinib Mylan be prescribed by physicians 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

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