25 July 2013
EMA/CHMP/447957/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Giotrif

afatinib

On 25 July 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Giotrif 20 mg, 30 mg, 40 mg and 50 mg film-coated tablets intended for the treatment of EGFR TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). The applicant for this medicinal product is Boehringer Ingelheim International GmbH. 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 Giotrif is afatinib, an antineoplastic agent, protein kinase inhibitor (L01XE13), that covalently binds to and irreversibly blocks signalling from all homo- and heterodimers formed by the ErbB family members EGFR (ErbB1), HER2 (ErbB2), ErbB3 and ErbB4.

The benefits with Giotrif have been shown in a phase III, randomised, open-label study of afatinib versus chemotherapy in patients with locally advanced or metastatic non-small cell lung cancer with activating EGFR mutation(s). In this study efficacy has been shown in terms of an increased progression free survival in patients receiving afatinib compared to chemotherapy. The most common side effects are diarrhea, stomatitis, rash, dermatitis acneiform, pruritus, dry skin, paronychia, decreased apetite and epistaxis.

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

The approved indication is: " GIOTRIF as monotherapy is indicated for the treatment of Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s) (see section 5.1)."

It is proposed that Giotrif be initiated and supervised 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

[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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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 Giotrif and therefore recommends the granting of the marketing authorisation.