31 January 2019
EMA/CHMP/34937/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vizimpro

dacomitinib

On 31 January 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vizimpro, intended for the treatment of patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) activating mutations. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Vizimpro will be available as film-coated tablets (15, 30 and 45 mg). The active substance of Vizimpro is dacomitinib, a pan-human EGFR (EGFR/HER1, HER2, and HER4) inhibitor, with activity against mutated EGFR with deletions in exon 19 or L858R substitution in exon 21 (ATC code: L01XE47).

The benefits with Vizimpro are its ability to increase progression free survival compared with gefitinib. The most common side effects are diarrhoea, rash, stomatitis, nail disorder, dry skin, decreased appetite, conjunctivitis, weight loss, alopecia, pruritus, increased transaminases and nausea.

The full indication is: "Vizimpro, as monotherapy, is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations". It is proposed that Vizimpro 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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