EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2018
EMA/CHMP/476013/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mektovi

binimetinib

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 Mektovi, intended for use in combination with encorafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. The applicant for this medicinal product is Pierre Fabre Medicament.

Mektovi will be available as a 15-mg film-coated tablets. The active substance of Mektovi is binimetinib, an antineoplastic agent (ATC code: L01XE41) that inhibits the kinase activity of mitogen-activated extracellular signal regulated kinase 1 (MEK1) and MEK2.

The benefits with the use of the combination, of Mektovi with encorafenib, are its ability to prolong progression-free survival and overall survival in melanoma patients that harbour the BRAFV600 mutation compared to vemurafenib (960mg twice a day). The most common side effects are fatigue, nausea, diarrhoea, vomiting, retinal detachment, abdominal pain, arthralgia, increased blood creatine kinase and myalgia.

The full indication is: “Binimetinib in combination with encorafenib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation”. It is proposed that Mektovi in combination with encorafenib should be initiated and supervised under the responsibility of a physician experienced in the use of anticancer medicinal products.

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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