26 July 2018
EMA/CHMP/476007/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Braftovi

encorafenib

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 Braftovi, intended for use in combination with binimetinib 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.

Braftovi will be available as 50 mg and 75 mg hard capsules. The active substance of Braftovi is encorafenib, an antineoplastic agent that inhibits the activity of the BRAF V600 kinase and subsequently blocks the MAPK pathway.

The benefits with the use of the combination, of Braftovi with binimetinib, are its ability to prolong progression free survival and overall survival in melanoma patients harbouring a BRAF V600 mutation compared to vemurafenib (960mg twice a day). The most common side effects are hyperkeratosis, alopecia, palmar-plantar erythrodysaesthesia syndrome, fatigue, rash, arthralgia, dry skin, nausea, myalgia, headache, vomiting and pruritus.

The full indication is: "Encorafenib in combination with binimetinib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation (see sections 4.4 and 5.1)." It is proposed that Braftovi in combination with binimetinib 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact