24 September 2015
EMA/CHMP/571584/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cotellic

cobimetinib

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cotellic, intended for the treatment of unresectable or metastatic melanoma in combination with vemurafenib. The applicant for this medicinal product is Roche Registration Ltd.

Cotellic will be available as 20 mg film-coated tablets. The active substance of Cotellic is cobimetinib, an antineoplastic agent (ATC code: L01) which blocks the mitogen-activated protein kinase (MAPK) pathway by targeting the kinases MEK1 and MEK2, thereby inhibiting intracellular signalling and decreasing tumour cell proliferation, and delaying the onset of resistance when compared to BRAF inhibitor monotherapy (vemurafenib).

The benefits with Cotellic are its ability to improve progression-free survival in melanoma patients with a BRAFV600 mutation compared with vemurafenib monotherapy. The most common side effects observed with a higher frequency in the Cotellic plus vemurafenib arm were diarrhoea, rash, nausea, pyrexia, photosensitivity reaction, increased alanine aminotransferase, increased aspartate aminotransferase, increased blood creatine phosphokinase, and vomiting.

The full indication is: “Cotellic is indicated for use in combination with vemurafenib 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 Cotellic in combination with vemurafenib should only be initiated and supervised by a qualified 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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