22 June 2017
EMA/CHMP/383155/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kisqali

ribociclib

On 22 June 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kisqali, intended for the treatment of locally advanced or metastatic breast cancer. The applicant for this medicinal product is Novartis Europharm Ltd.

Kisqali will be available as 200-mg film-coated tablets. The active substance of Kisqali is ribociclib, a protein kinase inhibitor (ATC code: L01XE42) that selectively inhibits cyclin-dependent kinase (CDK) 4 and 6. CDK4 and 6 are downstream of multiple signalling pathways which lead to cellular proliferation.

The approval was based on a study showing that Kisqali in combination with letrozole (an aromatase inhibitor) significantly improves progression-free survival. The most common side effects are neutropenia, leukopenia, headache, back pain, nausea, fatigue, diarrhoea, vomiting, constipation, alopecia and rash.

The full indication is: "Kisqali in combination with an aromatase inhibitor is indicated for the treatment of postmenopausal women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer as initial endocrine based therapy".

It is proposed that Kisqali 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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