15 September 2016
EMA/CHMP/597497/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ibrance

palbociclib

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ibrance, intended for the treatment of locally advanced or metastatic breast cancer. The applicant for this medicinal product is Pfizer Limited.

Ibrance will be available as 75, 100 and 125 mg hard capsules. The active substance of Ibrance is palbociclib, a protein kinase inhibitor (ATC code: L01XE33) that is a highly selective, reversible inhibitor of cyclin-dependent kinases (CDK) 4 and 6. CDK4 and 6 are downstream of multiple signalling pathways which lead to cellular proliferation.

The approval was based on studies showing that IBRANCE in combination with letrozole (an aromatase inhibitor) or fulvestrant, significantly improves progression-free survival. The most common side effects are neutropenia, infections, leukopenia, fatigue, nausea, stomatitis, anaemia, alopecia, and diarrhoea.

The full indication is:

“Ibrance is indicated for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer:

- in combination with an aromatase inhibitor;
- in combination with fulvestrant in women who have received prior endocrine therapy (see section 5.1).

In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone releasing hormone (LHRH) agonist.”

It is proposed that treatment with Ibrance should be initiated and supervised by 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

[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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