28 May 2020
EMA/CHMP/266002/2020
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Piqray

alpelisib

On 28 May 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Piqray, intended for the treatment of locally advanced or metastatic breast cancer with a PIK3CA mutation. The applicant for this medicinal product is Novartis Europharm Limited.

Piqray will be available as 50-mg, 150-mg and 200-mg film-coated tablets. The active substance of Piqray is alpelisib, a α-specific class-I phosphatidylinositol-3-kinase (PI3Kα) inhibitor (ATC code: L01XX65). Gain of function mutations in the gene encoding the catalytic α subunit of PI3K (PIK3CA) lead to activation of PI3Kα and AKT signalling, cellular transformation and the development of tumours. Alpelisib inhibits the phosphorylation of PI3K downstream targets, including AKT, which are involved in cellular proliferation.

The benefits with Piqray are its ability to significantly improve progression-free survival in combination with fulvestrant. The most common side effects are increased plasma glucose and creatinine, diarrhoea, increased gamma glutamyltransferase, rash, lymphopenia, nausea, increased alanine aminotransferase, anaemia, fatigue, increased blood lipase, loss of appetite, stomatitis, vomiting, weight loss, hypocalcaemia, falls in plasma glucose, prolongation of activated partial thromboplastin time (aPTT) and alopecia.

The full indication is:

> Piqray is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine therapy as monotherapy.

It is proposed that Piqray be prescribed by physicians experienced in the use of cancer treatments.

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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