15 November 2018
EMA/774653/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Orkambi

lumacaftor / ivacaftor

On 15 November 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Orkambi. The marketing authorisation holder for this medicinal product is Vertex Pharmaceuticals (Europe) Ltd.

The CHMP recommended the approval of two new presentations of Orkambi (100 mg/125 mg and 150 mg/188 mg granules in sachet) for use in children aged 2 years and older. The currently authorised presentations (100 mg/125 mg and 200 mg/125 mg tablets) are for children aged 6 years and above.

The full indication for the new Orkambi granules will be:

“Orkambi granules are indicated for the treatment of cystic fibrosis (CF) in children aged 2 years and older who are homozygous for the *F508del* mutation in the CFTR gene”.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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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