9 November 2017
EMA/738556/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Orkambi

lumacaftor / ivacaftor

On 9 November 2017, 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 adopted an extension to the existing indication as follows[2]:

Orkambi is indicated for the treatment of cystic fibrosis (CF) in patients aged ~~12~~ **6** years and older who are homozygous for the *F508del* mutation in the *CFTR* gene (see sections **4.2**, 4.4 and 5.1).

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
[2] New text in bold, removed text as strikethrough

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact