21 April 2017
EMA/CHMP/219462/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Celsentri

Maraviroc

On 21 April 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 Celsentri. The marketing authorisation holder for this medicinal product is ViiV Healthcare UK Limited.

The CHMP adopted an extension to an existing indication as follows[2]:

"Celsentri, in combination with other antiretroviral medicinal products, is indicated for treatment-experienced adult**s, adolescents and children of 2 years of age and older and weighing at least 10 kg** ~~patients~~ infected with only CCR5-tropic HIV-1 detectable (see section**s** 4.2 **and 5.1**).

~~This indication is based on safety and efficacy data from two double-blind, placebo-controlled trials in treatment-experienced patients (see section 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

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