EMA/624833/2015

# European Medicines Agency decision

P/0237/2015

of 30 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for maraviroc (Celsentri), (EMEA-000020-PIP01-07-M05) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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# European Medicines Agency decision

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/109/2008 issued on 1 December 2008, the decision P/311/2011 issued on 22 December 2011, and the decision P/0224/2014 issued on 5 September 2014,

Having regard to the application submitted by ViiV Healthcare UK Ltd on 18 June 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral, and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 September 2015, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral, and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

(3) It is therefore appropriate to adopt a decision on the granting of a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for maraviroc (Celsentri), film-coated tablet, oral solution, oral use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

A waiver for maraviroc (Celsentri), film-coated tablet, oral solution, oral use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 3***

This decision is addressed to ViiV Healthcare UK Ltd, 980 Great West Road, TW8 9GS – Brentford, United Kingdom.

Done at London, 30 October 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/442145/2015
London, 11 September 2015

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000020-PIP01-07-M05

## Scope of the application

**Active substance(s):**

Maraviroc

**Invented name:**

Celsentri

**Condition(s):**

Treatment of human immunodeficiency virus (HIV-1) infection

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Film-coated tablet

Oral solution

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

ViiV Healthcare UK Ltd

**Information about the authorised medicinal product:**

See Annex II

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## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ViiV Healthcare UK Ltd submitted to the European Medicines Agency on 18 June 2015 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/109/2008 issued on 1 December 2008, the decision P/311/2011 issued on 22 December 2011 and the decision P/0224/2014 issued on 5 September 2014.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver.

The procedure started on 14 July 2015.

## Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion;
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 1. Waiver

## *1.1. Condition:*

Treatment of human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- film-coated tablet, oral solution, oral use;

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of human immunodeficiency virus (HIV-1) infection

### 2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus (HIV-1) infection, in combination with other antiretroviral medicinal products, in treatment-experienced children infected with only CCR5-tropic HIV-1 detectable.

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Film-coated tablet

Oral solution

### 2.1.4. Measures

| Area | Number of studies | Description |
|---|---|---|
| Quality-related studies | 2 | **Study 1**<br>Development of film-coated tablets<br>**Study 2**<br>Development of an age appropriate oral formulation |
| Non-clinical studies | 0 | Not applicable. |

| | | |
|---|---|---|
| Clinical studies | 1 | **Study 3**<br><br>Open-label, two-stage, non-comparative, multi-center study to evaluate the safety, tolerability and pharmacokinetics/dosing of multiple doses of maraviroc combined with optimised background therapy (OBT) in antiretroviral (ARV) treatment-experienced children and adolescents from 2 to less than 18 years.<br><br>**Study 4** deleted in EMEA-000020-PIP01-07-M05. |
| Extrapolation, modelling and simulation studies | 0 | Not applicable. |
| Other studies | 0 | Not applicable. |
| Other measures | 0 | Not applicable. |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By June 2015 |
| Deferral for one or more measures contained in the paediatric investigation plan: | No |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s):

1. Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

- Celsentri, in combination with other antiretroviral medicinal products, is indicated for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable.

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

## Authorised pharmaceutical form(s):

Film-coated tablet

## Authorised route(s) of administration:

Oral use