EMA/469464/2014

European Medicines Agency decision

P/0224/2014

of 5 September 2014

on the acceptance of a modification of an agreed paediatric investigation plan for maraviroc (Celsentri), (EMEA-000020-PIP01-07-M04) 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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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, and the decision P/311/2011 issued on 22 December 2011,

Having regard to the application submitted by ViiV Healthcare UK Limited on 4 April 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 July 2014, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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,

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

[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, 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

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

Done at London, 5 September 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/291525/2014

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

EMEA-000020-PIP01-07-M04

Scope of the application

Active substance(s):

Maraviroc

Invented name:

Celsentri

Condition(s):

Treatment of Human immunodeficiency virus 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 Limited

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 Limited submitted to the European Medicines Agency on 4 April 2014 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, and the decision P/311/2011 issued on 22 December 2011.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 21 May 2014.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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 in the scope set out in the Annex I of this opinion.

   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 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.

London, 18 July 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of Human immunodeficiency virus 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 birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet for oral use.

Oral solution for oral use.

2.1.4. Measures

Area	Number of studies	Description
Quality	Total number of quality studies: 2	**Study 1:** Development of the film-coated tablet **Study 2:** Development of an age appropriate oral formulation
Non-clinical	Total number of studies	Not applicable.
Clinical	Total number of studies: 2	**Study 3:** 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. **Study 4:** Open-label, non-randomised, non-comparative, multi-center study to evaluate the safety, tolerability and pharmacokinetics of multiple doses of maraviroc in children infected with CCR5 tropic HIV-1 from birth to less than 2 years of age. The applicant must rediscuss with the PDCO the need for such study as well as the measures and timelines prior to its initiation

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 December 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of Human immunodeficiency virus 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 (see section 4.2).

This indication is based on safety and efficacy data from two double-blind, placebo-controlled trials in treatment-experienced patients (see section 5.1).

Authorised pharmaceutical form(s):

Film coated tablet

Authorised route(s) of administration:

Oral use