EMA/654883/2017

European Medicines Agency decision

P/0312/2017

of 30 October 2017

on the acceptance of a modification of an agreed paediatric investigation plan for cabotegravir (EMEA-001418-PIP01-13-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for cabotegravir (EMEA-001418-PIP01-13-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0272/2014 issued on 27 October 2014,

Having regard to the application submitted by ViiV Healthcare UK Limited on 23 June 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 September 2017, 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 cabotegravir, tablet, age-appropriate oral dosage form, suspension for injection, oral use, intramuscular 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, Middlesex, United Kingdom.

EMA/PDCO/420211/2017
London, 15 September 2017

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

EMEA-001418-PIP01-13-M01

Scope of the application

Active substance(s):

Cabotegravir

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Tablet

Age-appropriate oral dosage form

Suspension for injection

Route(s) of administration:

Oral use

Intramuscular use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK Limited

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 23 June 2017 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0272/2014 issued on 27 October 2014.

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

The procedure started on 18 July 2017.

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 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 annex 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;
- tablet, age-appropriate oral dosage form, suspension for injection; oral use, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

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 agents

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Age-appropriate oral dosage form

Suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate formulation
Non-clinical studies	0	Not applicable
Clinical studies	3	**Study 2** deleted in EMEA-001418-PIP01-13-M01

		Study 3 Multi-centre, open-label, non-comparative study to evaluate the pharmacokinetics, safety, tolerability, acceptability, maintenance and durability of suppression of a regimen of cabotegravir (CAB) oral and long-acting (LA) formulations and rilpivirine (RPV) oral and LA formulations in virologically suppressed adolescents from 12 to less than 18 years of age with HIV-1. **Study 4** Multi-centre, open-label, non-comparative study to evaluate pharmacokinetics, safety and tolerability of cabotegravir (oral and long-acting formulations) in children from 2 to less than 12 years of age with HIV-1. **Study 5** Multi-centre, open-label, non-comparative study to evaluate the safety, tolerability, acceptability, maintenance and durability of suppression of a regimen of cabotegravir long-acting formulation and rilpivirine long-acting formulation after induction of virologic suppression in children from 2 to less than 12 years of age with HIV-1.
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 December 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes