EMA/709107/2022

European Medicines Agency decision

P/0396/2022

of 9 September 2022

on the acceptance of a modification of an agreed paediatric investigation plan for cabotegravir (Vocabria), (EMEA-001418-PIP01-13-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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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 Union procedures for the authorisation and supervision of medicinal products for human 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, the decision P/0312/2017 issued on 30 October 2017, P/0354/2020 issued on 9 September 2020 and the decision P/0040/2022 issued on 31 January 2022,

Having regard to the application submitted by ViiV Healthcare UK Limited on 22 April 2022 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 22 July 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for cabotegravir (Vocabria), film-coated tablet, age-appropriate oral dosage form, prolonged-release 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, United Kingdom.

EMA/PDCO/244470/2022
Amsterdam, 22 July 2022

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

EMEA-001418-PIP01-13-M05

Scope of the application

Active substance(s):

Cabotegravir

Invented name:

Vocabria

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral dosage form

Prolonged-release suspension for injection

Route(s) of administration:

Oral use

Intramuscular use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK Limited

Information about the authorised medicinal product:

See Annex II

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 22 April 2022 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 decision P/0312/2017 issued on 30 October 2017, P/0354/2020 issued on 9 September 2020 and the decision P/0040/2022 issued on 31 January 2022.

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

The procedure started on 23 May 2022.

Scope of the modification

Some measures and timelines 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 Paediatric Committee member of Norway 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, age-appropriate oral dosage form, prolonged-release 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)

Film-coated tablet

Age-appropriate oral dosage form

Prolonged-release suspension for injection

2.1.4. Measures

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

	Study 3 Multi-centre, open-label, non-comparative study to evaluate the pharmacokinetics, safety, tolerability and acceptability, of cabotegravir (CAB) oral and long-acting (LA) formulations and rilpivirine (RPV) oral and LA formulations in virologically suppressed adolescents from 12 years to less than 18 years of age with HIV-1 infection. *This study is the same as study 1 of the rilpivirine EMEA-000317-PIP02-18-M01 and subsequent modifications thereof.* **Study 4** Deleted in procedure EMEA-001418-PIP01-13-M04 **Study 5** Deleted in procedure EMEA-001418-PIP01-13-M04 **Study 6** Added in procedure EMEA-001418-PIP01-13-M04 Multi-centre, open-label, non-comparative study to evaluate pharmacokinetics, safety and tolerability of cabotegravir + rilpivirine [oral and long acting formulations (LA)] in children from 2 years to less than 12 years of age with HIV-1. *This study is the same as study 2 of the rilpivirine EMEA-000317-PIP02-18-M01 and subsequent modifications thereof.*
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	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 September 2025
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 (HIV-1) infection

Authorised indication(s):

- Vocabria tablets are indicated in combination with rilpivirine tablets for the short-term treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class for:
  - oral lead in to assess tolerability of Vocabria and rilpivirine prior to administration of long acting cabotegravir injection plus long acting rilpivirine injection.
  - oral therapy for adults who will miss planned dosing with cabotegravir injection plus rilpivirine injection
- Vocabria injection is indicated, in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class.

Authorised pharmaceutical form(s):

Prolonged-release suspension for injection

Film-coated tablets

Authorised route(s) of administration:

Intramuscular use

Oral use