EMA/150156/2022 Corr

European Medicines Agency decision

P/0102/2022

of 17 March 2022

on the acceptance of a modification of an agreed paediatric investigation plan for cabotegravir (Vocabria), (EMEA-001418-PIP02-15-M03) 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/0216/2016 issued on 12 August 2016 and decision P/0118/2021 issued on 17 March 2021,

Having regard to the application submitted by ViiV Healthcare UK Limited on 22 November 2021 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 25 February 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 and to the deferral.

(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.

[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), prolonged-release suspension for injection, film-coated tablet, intramuscular use, 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

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0272/2014 issued on 27/10/2014, including subsequent modifications thereof.

Article 3

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

EMA/PDCO/735046/2021
Amsterdam, 25 February 2022

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

EMEA-001418-PIP02-15-M03

Scope of the application

Active substance(s):

Cabotegravir

Invented name:

Vocabria

Condition(s):

Prevention of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Prolonged-release suspension for injection

Film-coated tablet

Route(s) of administration:

Intramuscular use

Oral 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 November 2021 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/0216/2016 issued on 12 August 2016 and decision P/0118/2021 issued on 17 March 2021.

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

The procedure started on 4 January 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 and to the deferral 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 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

Prevention of human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 12 years;
- prolonged- release suspension for injection, film-coated tablet, intramuscular use, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Prevention of human immunodeficiency virus (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of HIV-1 acquisition in sexually active adolescents at high risk, from 12 to less than 18 years of age

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

From 12 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection, film-coated tablet

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Deleted in procedure EMEA-001418-PIP02-15-M03
Non-clinical studies	Not applicable
Clinical studies	Not applicable
Extrapolation, modelling and simulation studies	**Study 2** Modelling and simulation study to evaluate PK/PD of cabotegravir for pre-exposure prophylaxis of HIV infection in combination with safer sex practices in sexually active adolescents at high risk from 12 to less than 18 years of age

	Study 3 Extrapolation study to evaluate the use of cabotegravir for pre-exposure prophylaxis of HIV infection in combination with safer sex practices in sexually active adolescents at high risk from 12 to less than 18 years of age.
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:	No
Date of completion of the paediatric investigation plan:	By March 2022
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 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 tablet

Authorised route(s) of administration:

Intramuscular use

Oral use