EMA/68460/2022

European Medicines Agency decision

P/0067/2022

of 11 March 2022

on the acceptance of a modification of an agreed paediatric investigation plan for fostemsavir (tromethamine) (Rukobia), (EMEA-001687-PIP01-14-M06) 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/0258/2015 issued on 30 October 2015, decision P/0198/2016 issued on 15 July 2016, decision P/0040/2019 issued on 29 January 2019, P/0268/2020 issued on 17 July 2020 and the decision P/0430/2021 issued on 29 October 2021,

Having regard to the application submitted by ViiV Healthcare UK Ltd on 18 October 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 21 January 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 fostemsavir (tromethamine) (Rukobia), prolonged-release tablet, 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 Ltd, 980 Great West Road, TW89GS – Brentford, United Kingdom.

EMA/PDCO/603311/2021
Amsterdam, 21 January 2022

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

EMEA-001687-PIP01-14-M06

Scope of the application

Active substance(s):

Fostemsavir (tromethamine)

Invented name:

Rukobia

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Prolonged-release tablet

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

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 October 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/0258/2015 issued on 30 October 2015, decision P/0198/2016 issued on 15 July 2016, decision P/0040/2019 issued on 29 January 2019, P/0268/2020 issued on 17 July 2020 and the decision P/0430/2021 issued on 29 October 2021.

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

The procedure started on 22 November 2021.

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 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 6 years of age;
- prolonged-release tablet, 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 HIV-1 infection as part of a combination therapy in paediatric patients who have no more than 2 remaining available fully active antiretroviral therapies

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Prolonged-release tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a prolonged-release tablet ***Study 2*** *deleted with EMEA-001687-PIP01-14-M03*
Non-clinical studies	2	**Study 3** Oral pre- and postnatal development study in rats **Study 4** Ten-week oral toxicity study in juvenile rats with 8 weeks of recovery

Clinical studies	2	**Study 5** Open-label, single-arm trial to evaluate pharmacokinetics, safety, antiviral activity and acceptability/palatability of fostemsavir in combination with optimised background therapy (OBT) in HIV-1 infected children and adolescents from 6 to less than 18 years of age who are failing their current combination antiretroviral therapy (cART) and have dual- or triple-class antiretroviral (ARV) resistance ***Study 6*** *deleted with EMEA-001687-PIP01-14-M03* **Study 7** Open-label, randomised study in healthy adult volunteers to determine the bioavailability of the prolonged-release tablet developed in Study 1 relative to the adult prolonged-release tablet ***Study 8*** *deleted with EMEA-001687-PIP01-14-M03*
Extrapolation, modelling and simulation studies	2	**Study 9** Modelling and simulation study to support the use of the fostemsavir in HIV-infected children and adolescents from 6 to less than 18 years of age who are failing their current cART and have dual- or triple-class ARV resistance **Study 10** Extrapolation study to support the use of the fostemsavir in HIV-infected children and adolescents from 6 to less than 18 years of age who are failing their current cART and have dual- or triple-class ARV resistance
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 July 2024
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 HIV-1 infection

Authorised indication(s):

- Rukobia, in combination with other antiretrovirals, is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.

Authorised pharmaceutical form(s):

Prolonged-release tablet

Authorised route(s) of administration:

Oral use