



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/388640/2023

European Medicines Agency decision P/0380/2023

of 7 September 2023

on the acceptance of a modification of an agreed paediatric investigation plan for fostemsavir (tromethamine), (Rukobia), (EMEA-001687-PIP01-14-M07) 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 726/2004¹,

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 Agency²,

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 and the decision P/0067/2022 issued on 11 March 2022,

Having regard to the application submitted by ViiV Healthcare UK Ltd on 20 April 2023 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 July 2023, 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 fostemsavir (tromethamine) (Rukobia), prolonged-release tablet, 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 is addressed to ViiV Healthcare UK Ltd, 980 Great West Road, TW89GS - Brentford, United Kingdom.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/203931/2023
Amsterdam, 21 July 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001687-PIP01-14-M07

Scope of the application

Active substance(s):

Fostemsavir (tromethamine)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Prolonged-release tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK Ltd

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 20 April 2023 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, the decision P/0198/2016 issued on 15 July 2016, the decision P/0040/2019 issued on 29 January 2019, the decision P/0268/2020 issued on 17 July 2020, the decision P/0430/2021 issued on 29 October 2021 and the decision P/0067/2022 issued on 11 March 2022.

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

The procedure started on 22 May 2023.



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 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 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	Description
Quality-related studies	Study 1 Development of a prolonged-release tablet Study 2 Deleted with EMEA-001687-PIP01-14-M03
Non-clinical studies	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	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, at least, dual-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	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, at least, dual-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, at least, dualclass ARV resistance.
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 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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.
 - Invented name(s): Rukobia
 - Authorised pharmaceutical form(s): prolonged-release tablet
 - Authorised route(s) of administration: oral use
 - Authorised via centralised procedure