MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100951-PIP01-23-M01)

MHRA-100951-PIP01-23-M02

Scope of the Application

Active Substance(s)

FOSTEMSAVIR TROMETHAMINE

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 Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ViiV Healthcare UK Limited submitted to the licensing authority on 31/03/2023 10:27 BST an application for a Modification

The procedure started on 24/07/2023 11:46 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100951-PIP01-23-M02

Of 29/08/2023 16:32 BST

On the adopted decision for FOSTEMSAVIR TROMETHAMINE (MHRA-100951-PIP01-23-M02) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for FOSTEMSAVIR TROMETHAMINE, Prolonged-release tablet , ORAL USE .

This decision is addressed to ViiV Healthcare UK Limited, 980 Great West Road, Brentford, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of human immunodeficiency virus (HIV-1) infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Prolonged-release tablet Route(s) of administration: ORAL USE Reason for granting waiver: 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(s):

Treatment of human immunodeficiency virus (HIV-1) infection

2.2 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.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Prolonged-release tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a prolonged-release tablet. Study 2 deleted during procedure 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 during procedure 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 during procedure EMEA-001687-PIP01-14-M03.
Extrapolation, Modeling & 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 a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	31/07/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes