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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100845-PIP01-23-M02

Scope of the Application

Active Substance(s)

CABOTEGRAVIR SODIUM

Condition(s)

Prevention of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Film-coated tablet; Prolonged-release suspension for injection

Route(s) of Administration

ORAL USE; INTRAMUSCULAR 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 03/02/2023 10:13 GMT an application for a Modification

The procedure started on 21/04/2023 10:19 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100845-PIP01-23-M02

Of 06/06/2023 17:51 BST

On the adopted decision for CABOTEGRAVIR (MHRA-100845-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 CABOTEGRAVIR, Film-coated tablet; Prolonged-release suspension for injection , ORAL USE; INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of human immunodeficiency virus (HIV-1) infection. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age. Pharmaceutical form(s): Film-coated tablet Prolonged-release suspension for injection Route(s) of administration: INTRAMUSCULAR USE ORAL USE Reason for granting waiver: 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(s):

Prevention of human immunodeficiency virus (HIV-1) infection.

2.2 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.

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

The paediatric population from 12 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Film-coated tablet Prolonged-release suspension for injection.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Deleted during procedure MHRA-100845-PIP01-23-M02.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	2	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 years 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 years to less than 18 years of age.
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:	No
Date of completion of the paediatric investigation plan:	31/03/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes