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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100901-PIP01-23-M01) and to the deferral

MHRA-100901-PIP01-23-M02

Scope of the Application

Active Substance(s)

CABOTEGRAVIR

Condition(s)

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Prolonged-release suspension for injection; Film-coated Tablet; Age-appropriate oral dosage form

Route(s) of Administration

INTRAMUSCULAR USE; 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 28/02/2023 12:00 GMT an application for a Modification

The procedure started on 11/08/2023 19:19 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 and to the deferral

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-100901-PIP01-23-M02

Of 01/09/2023 10:03 BST

On the adopted decision for CABOTEGRAVIR (MHRA-100901-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, Prolonged-release suspension for injection; Film-coated Tablet; Age-appropriate oral dosage form , INTRAMUSCULAR, 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 2 years of age. Pharmaceutical form(s): Prolonged-release suspension for injection; Film-coated Tablet; Age-appropriate oral dosage form Route(s) of administration: INTRAMUSCULAR USE; ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

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 human immunodeficiency virus (HIV-1) infection, in combination with other antiretroviral agents.

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

The paediatric population from 2 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Prolonged-release suspension for injection; Film-coated Tablet; Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 deleted during procedure EMEA-001418-PIP01-13-M01. Study 3 Multi-centre, open-label, non-comparative study to evaluate the pharmacokinetics, safety, tolerability and acceptability cabotegravir (CAB) oral and long-acting (LA) formulations and rilpivirine (RPV) oral and LA formulations in virologically suppressed adolescents from 12 years to less than 18 years of age with HIV-1. This is same as study 1 in the agreed PIP MHRA-100865-PIP01-23-M01 for rilpivirine and subsequent modifications thereof. Study 4 deleted during procedure MHRA-100901-PIP01-23-M01. Study 5 deleted during procedure MHRA-100901-PIP01-23-M01. Study 6 (Added during procedure MHRA-100901-PIP01-23-M01.) Multi-centre, open-label, non-comparative study to evaluate pharmacokinetics, safety and tolerability of cabotegravir + rilpivirine [oral and long acting

		formulations (LA)] in children from 2 years to less than 12 years of age with HIV-1. This is same as study 2 in the agreed PIP MHRA-100865-PIP01-23-M01 for rilpivirine and subsequent modifications thereof.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	30/09/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes