MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101812-PIP01-25

Scope of the Application

Active Substance(s)

BICTEGRAVIR; LENACAPAVIR SODIUM

Condition(s)

Treatment of human immunodeficiency virus type 1 (HIV-1) infection

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral solid dosage form.

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Gilead Sciences Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Gilead Sciences Ltd submitted to the licensing authority on 19/03/2025 14:47 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/04/2025 13:28 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-101812-PIP01-25

Of 16/06/2025 07:11 BST

On the adopted decision for BICTEGRAVIR; LENACAPAVIR SODIUM (MHRA-101812-PIP01-25) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for BICTEGRAVIR; LENACAPAVIR SODIUM, Film-coated tablet; Age-appropriate oral solid dosage form. , ORAL USE .

This decision is addressed to Gilead Sciences Ltd, 280 High Holborn, London, UNITED KINGDOM, WC1V 7EE

ANNEX I

1. Waiver

1.1 Condition:

Treatment of human immunodeficiency virus type 1 (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): Film-coated tablet Age-appropriate oral solid dosage form 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 over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of human immunodeficiency virus type 1 (HIV-1) infection

2.2 Indication(s) targeted by the PIP:

Treatment of HIV-1 infection in patients ≥ 2 to 18 years of age weighing ≥ 10 kg to replace the current ARV regimen in those who have been virologically suppressed for at least 6 months with no known substitutions associated with resistance to the individual components of bictegravir (BIC) / lenacapavir (LEN).

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):

Film-coated tablet Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral formulation of the fixeddose combination (FDC) bictegravir/lenacapavir (BIC/LEN) for use in children from 2 years of age, weighing from 10 to less than 35 kg. Study 2 Development of age-appropriate oral loading-dose formulation of lenacapavir for use in children from 2 years of age, weighing from 10 to less than 35 kg.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 3 (GS-US-621-6463) Open-label, multicentre, single-arm study to evaluate the pharmacokinetics (PK), safety, tolerability, and antiviral activity of the oral FDC bictegravir/lenacapavir in virologically suppressed paediatric participants from 2 years to less than 18 years of age with HIV-1 infection.
Extrapolation, Modeling & Simulation Studies	2	Study 4 Modelling and simulation study to support dose finding of bictegravir and lenacapavir in the oral FDC bictegravir/ lenacapavir in paediatric patients from 2 years to less than 18 years of age with HIV-1 infection. Extrapolation plan Study 3 (GS-US-621-6463) and Study 4 are part of an extrapolation plan covering

		the paediatric population from 2 years to less than 18 years of age with HIV-1 infection.
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:	30/06/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes