MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-101174-PIP01-23

Scope of the Application

Active Substance(s)

LENACAPAVIR SODIUM

Condition(s)

Prevention of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Solution for injection; Film-coated tablet

Route(s) of Administration

SUBCUTANEOUS USE, 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 17/11/2023 11:40 GMT an application for a Paediatric Investigation Plan

The procedure started on 12/02/2024 07:21 GMT

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-101174-PIP01-23

Of 23/10/2024 10:03 BST

On the adopted decision for LENACAPAVIR SODIUM (MHRA-101174-PIP01-23) 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 LENACAPAVIR SODIUM, Solution for injection; Film-coated tablet , SUBCUTANEOUS USE, 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:

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): Solution for injection Film-coated tablet Route(s) of administration: SUBCUTANEOUS 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:

Prevention of human immunodeficiency virus (HIV-1) infection

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):

Solution for injection Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1: GS-US-412-5624 (PURPOSE 1) Randomised, double-blind, multicentre, trial to evaluate safety and efficacy of subcutaneous lenacapavir (LEN) and oral emtricitabine/tenofovir alafenamide (F/TAF) for pre-exposure prophylaxis (PrEP) in adolescent girls from 16 to less than 18 years of age and young women at risk of HIV infection. Study 2: GS-US-528-9023 (PURPOSE 2) Randomised double-blind, multicentre, study to evaluate efficacy and safety of subcutaneous lenacapavir (LEN) for HIV pre-exposure prophylaxis (PrEP) in cisgender males, transgender female, transgender males, and gender nonbinary people from 16 years of age (and adults) who have sex with male partners and are at risk for HIV infection.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation to support extrapolation of safety and efficacy data and determine the dose for adolescents from 12 years to less than 18 years old weighing $\geq$ 35 kg for pre-exposure prophylaxis (PrEP). Extrapolation Plan Studies 1, 2 and 3 (modelling and simulation

		study) are part of the extrapolation of efficacy and safety data from adults and adolescents 16 years and older weighing at least 35 kg to adolescents of age 12 years to less than 18 years weighing at least 35 kg for the prevention of human immunodeficiency virus (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:	31/07/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes