EMA/307434/2024

# European Medicines Agency decision

P/0271/2024

of 19 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for lenacapavir sodium (Sunleca), (EMEA-002740-PIP01-19-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0005/2021 issued on 15 January 2021,

Having regard to the application submitted by Gilead Sciences International Ltd on 25 March 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 June 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

***Article 1***

Changes to the agreed paediatric investigation plan for lenacapavir sodium (Sunleca), age-appropriate oral solid dosage form, film-coated tablet, solution for injection, oral use, subcutaneous use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to Gilead Sciences International Ltd., Granta Park, Flowers Building, Great Abington, CB21 6GT – Cambridge, United Kingdom.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

EMA/PDCO/142427/2024
Amsterdam, 28 June 2024

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002740-PIP01-19-M01

## Scope of the application

**Active substance(s):**

Lenacapavir (sodium)

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of human immunodeficiency virus (HIV-1) infection

**Pharmaceutical form(s):**

Age-appropriate oral solid dosage form

Film-coated tablet

Solution for injection

**Route(s) of administration:**

Oral use

Subcutaneous use

**Name/corporate name of the PIP applicant:**

Gilead Sciences International Ltd

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd submitted to the European Medicines Agency on 25 March 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0005/2021 issued on 15 January 2021.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 29 April 2024.

## Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 1. Waiver

## *1.1. Condition:*

Treatment of human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- age-appropriate oral solid dosage form, film-coated tablet, solution for injection, oral use; subcutaneous use;
- 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:*

Treatment of human immunodeficiency virus (HIV-1) infection

### 2.1.1. Indication(s) targeted by the PIP

Heavily treated experienced (HTE) children and adolescents (from 6 to less than 18 years of age): in combination with an optimised background regimen for the treatment of patients infected with multidrug resistant (MDR) HIV-1 infection

Virologically suppressed (VS) children and adolescents (from 2 to less than 18 years of age): in combination with partner agent as a complete regimen for the treatment of children and adolescents living with HIV-1 to replace the current antiretroviral therapy (ARV) regimen in those who are VS (HIV-1 RNA < 50 copies/mL) on a stable ARV regimen.

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Age-appropriate oral solid dosage form

Film-coated tablet

Solution for injection

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | **Study 1**<br><br>Development of an oral formulation for use in children from 2 to less than 12 years |

| | |
|---|---|
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 2 (GS-US-563-5958)**<br><br>Open-label, single-arm, multicohort study to evaluate pharmacokinetics (PK), safety, tolerability, and activity of lenacapavir from 2 to less than 18 years of age with HIV infection, who are virologically suppressed (VS) (GS-US-563-5958). |
| Extrapolation, modelling and simulation studies | **Study 3**<br><br>Development of a population PK model in the adult population to predict lenacapavir exposures in HTE and VS paediatric subjects for 2 to less than 18 years of age and support LEN paediatric dosing.<br><br>**Study 4**<br><br>Analysis of similarity in exposure-response relationship to support the extrapolation of efficacy of lenacapavir in HTE children and adolescents from 6 to less than 18 years of age. |
| Other studies | Not applicable |
| Other measures | Not applicable |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By December 2027 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

## Condition(s) and authorised indication(s)

1. Treatment of HIV-1 infection

Authorised indication(s):

- Sunlenca injection, in combination with other antiretroviral(s), is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen
  - Invented name(s): Sunleca
  - Authorised pharmaceutical form(s): solution for injection
  - Authorised route(s) of administration: injection
  - Authorised via centralised procedure