

EMA/284569/2023

European Medicines Agency decision

P/0265/2023

of 14 July 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bictegrovir / lenacapavir (EMA-003324-PIP01-22) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Gilead Sciences International Ltd. on 12 September 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 May 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for bictegravir / lenacapavir, film-coated tablet, age-appropriate oral solid dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for bictegravir / lenacapavir, film-coated tablet, age-appropriate oral solid dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for bictegravir / lenacapavir, film-coated tablet, age-appropriate oral solid dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

EMA/PDCO/95916/2023 Corr¹
Amsterdam, 26 May 2023

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-003324-PIP01-22

Scope of the application

Active substance(s):

Bictegravir / lenacapavir

Invented name and authorisation status:

See Annex II

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 International Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd. submitted for agreement to the European Medicines Agency on 12 September 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 17 October 2022.

¹ 19 June 2023

Supplementary information was provided by the applicant on 20 February 2023. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Paediatric Committee members of Norway agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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)

Waiver

1.1. Condition:

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

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- film-coated tablet and age-appropriate dosage form; oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

2. Paediatric investigation plan

2.1. Condition:

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

2.1.1. Indication(s) targeted by the PIP

Treatment of HIV-1 infection in paediatric patients aged at least 2 years to less than 18 years to replace the current ARV regimen in those who have been virologically suppressed on a stable anti-retroviral regimen for at least 6 months with no known substitutions associated with resistance to either agent of the Fixed Dose Combination (FDC) of bictegravir (BIC) / lenacapavir (LEN).

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate dosage form

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Development of an age-appropriate oral formulation of the fixed-dose 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	Not applicable
Clinical studies	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.
Modelling and simulation studies	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.
Other studies	Not applicable
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, as agreed by the PDCO.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2028
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:

The product is not authorised anywhere in the European Community.