EMA/358271/2021

European Medicines Agency decision

P/0269/2021

of 9 July 2021

on the acceptance of a modification of an agreed paediatric investigation plan for tenofovir alafenamide (Vemlidy), (EMEA-001584-PIP01-13-M06) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0209/2014 issued on 11 August 2014, decision P/0221/2016 issued on 12 August 2016, decision P/0274/2017 issued on 4 October 2017, decision P/0037/2018 issued on 30 January 2018, decision P/0133/2019 issued on 17 April 2019, and decision P/0063/2020 issued on 20 February 2020,

Having regard to the application submitted by Gilead Sciences International Ltd on 15 February 2021 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 21 May 2021, 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.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for tenofovir alafenamide (Vemlidy), film-coated tablet, age appropriate non-tablet formulation, oral use, 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, CB21 6GT- Cambridge, United Kingdom.

EMA/PDCO/107737/2021
Amsterdam, 21 May 2021

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

EMEA-001584-PIP01-13-M06

Scope of the application

Active substance(s):

Tenofovir alafenamide

Invented name:

Vemlidy

Condition(s):

Treatment of chronic viral hepatitis B

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Age appropriate non-tablet formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd

Information about the authorised medicinal product:

See Annex II

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 15 February 2021 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/0209/2014 issued on 11 August 2014, decision P/0221/2016 issued on 12 August 2016, decision P/0274/2017 issued on 4 October 2017, decision P/0037/2018 issued on 30 January 2018, decision P/0133/2019 issued on 17 April 2019, and decision P/0063/2020 issued on 20 February 2020.

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

The procedure started on 23 March 2021.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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 chronic viral hepatitis B

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- film-coated tablet, age appropriate non-tablet formulation, oral use;
- 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

Treatment of chronic viral hepatitis B

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic hepatitis B infection

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 non-tablet formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1** *(deleted during procedure EMEA-001584-PIP01-13-M06)* **Study 2** Development of an age appropriate oral non-tablet formulation
Non-clinical studies	0	Not applicable

Clinical studies	2	**Study 3** *(deleted during procedure EMEA-001584-PIP01-13-M02)* **Study 4** Double-blind, placebo-controlled, pharmacokinetic, efficacy, safety, tolerability and antiviral activity study of tenofovir alafenamide administered for 24 weeks followed by 24 weeks open label extension phase in treatment naïve and treatment experienced, HBeAg-positive and HBeAg-negative children (2 to less than 12 years of age) with chronic hepatitis B infection. **(Cohort 2 of GS-US-320-1092)** **Study 5** Open-label, relative bioavailability study of the proposed age-appropriate paediatric formulation in healthy adult volunteers. **(GS-US-320-1196)**
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	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 September 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of chronic hepatitis B

Authorised indication(s):

- Vemlidy is indicated for the treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg)

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use