EMA/593114/2020

European Medicines Agency decision

P/0435/2020

of 13 November 2020

on the acceptance of a modification of an agreed paediatric investigation plan for elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide (Genvoya) (EMEA-001460-PIP01-13-M05) 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/0026/2014 issued on 24 January 2014, the decision P/0195/2015 issued on 4 September 2015, the decision P/0211/2017 issued on 9 August 2017 and the decision P/0202/2020 issued on 27 May 2020,

Having regard to the application submitted by Gilead Sciences International Ltd. on 6 July 2020 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 16 October 2020, 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.

[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 elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide (Genvoya), film-coated tablet, oral 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., Flowers Building, Granta Park, Great Abington, CB21 6GT - Cambridge, United Kingdom.

EMA/PDCO/410780/2020
Amsterdam, 16 October 2020

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

EMEA-001460-PIP01-13-M05

Scope of the application

Active substance(s):

Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide

Invented name:

Genvoya

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

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 6 July 2020 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/0026/2014 issued on 24 January 2014, the decision P/0195/2015 issued on 4 September 2015, the decision P/0211/2017 issued on 9 August 2017 and the decision P/0202/2020 issued on 27 May 2020.

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

The procedure started on 18 August 2020.

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 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 human immunodeficiency virus type 1 (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- film-coated tablet, oral 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 type 1 (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus type 1 (HIV-1) infection in paediatric patients from 6 years to less than 18 years

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate film-coated tablet for use in children from 6 to less than 12 years of age.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 2** Open-label, single-arm trial to evaluate the pharmacokinetics (PK), safety, tolerability, and antiviral activity of the elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide single tablet regimen (E/C/F/TAF STR) in HIV-1 infected antiretroviral treatment-naive, adolescents (from 12 to less than 18 years of age) (Cohort 1) and virologically suppressed children (from 6 to less

		than 12 years of age weighing at least 25 kg (Cohort 2), and less than 25 kg (Cohort 3). *This study is the same as study 8 of the emtricitabine / tenofovir alafenamide PIP EMEA-001577-PIP02-14-M01 and subsequent modifications thereof.* **Study 3** Open-label, multicentre, single-arm trial to evaluate the safety, tolerability, and antiviral activity of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) in virologically suppressed HIV-1 infected adolescents (from 12 to less than 18 years of age) who are pretreated without resistance. **Study 4** Study deleted in EMEA-001460-PIP01-13-M04.

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 April 2021
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):

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

Authorised indication(s):

- Genvoya is indicated for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus 1 (HIV 1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use