EMA/688246/2015

European Medicines Agency decision

P/0265/2015

of 6 November 2015

on the acceptance of a modification of an agreed paediatric investigation plan for elvitegravir (Vitekta), (EMEA-000968-PIP02-11-M04) 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/0010/2012 issued on 24 January 2012, the decision P/0066/2013 issued on 26 March 2013, the decision P/0186/2013 issued on 2 August 2013, and the decision P/0310/2013 issued on 19 December 2013,

Having regard to the application submitted by Gilead Sciences International Ltd on 20 July 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 October 2015, 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 elvitegravir (Vitekta), film coated tablet, dispersible tablet, 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, Abington, CB21 6GT – Cambridge, United Kingdom.

Done at London, 6 November 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/532986/2015
London, 9 October 2015

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

EMEA-000968-PIP02-11-M04

Scope of the application

Active substance(s):

Elvitegravir

Invented name:

Vitekta

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film coated tablet

Dispersible 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

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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 20 July 2015 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0010/2012 issued on 24 January 2012, the decision P/0066/2013 issued on 26 March 2013, the decision P/0186/2013 issued on 2 August 2013, and the decision P/0310/2013 issued on 19 December 2013.

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

The procedure started on 11 August 2015.

Scope of the modification

Some measures and 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 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 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of human immunodeficiency virus (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

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

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Film coated tablet;
- Dispersible tablet.

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	2	**Study 1:** Development of age-appropriate film-coated tablet for oral use. **Study 2:** Development of a dispersible tablet for oral suspension.
Non-clinical studies	0	Not applicable.
Clinical studies	4	**Study 3:** Randomised, open-label, crossover study in healthy adult subjects to determine the relative bioavailability of adult elvitegravir film-coated tablet to an age appropriate tablet (Cohort 1) and to an age appropriate powder for oral suspension formulation (Cohort 2). **Study 4:** An open-label, multi-cohort, 2-part study evaluating pharmacokinetics, safety, and anti-viral activity of elvitegravir administered with an optimised background regimen containing a ritonavir-boosted protease inhibitor (PI/r) in HIV-1 infected paediatric patients.

Area	Number of studies	Description
		Study 5: Open-label, randomised, non-inferiority trial in HIV-1 infected patients from 6 to less than 18 years responsive to stable antiretroviral therapy (ART) containing any boosted PI or NNRTI and 2 nucleoside reverse transcriptase inhibitors (NRTIs) with no history of darunavir (DRV) or integrase inhibitor mutations. **Study 6:** A multicentre, open-label, non-randomised, multicohort study to evaluate the pharmacokinetics, safety and antiviral activity of cobicistat-boosted elvitegravir in HIV-1 infected, antiretroviral treatment-naive paediatric patients.
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:	No
Date of completion of the paediatric investigation plan:	By April 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

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

Authorised indication(s):

- Vitekta co-administered with a ritonavir-boosted protease inhibitor and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults who are infected with HIV-1 without known mutations associated with resistance to elvitegravir

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use