EMA/291491/2018

European Medicines Agency decision

P/0151/2018

of 18 May 2018

on the acceptance of a modification of an agreed paediatric investigation plan for lamivudine/dolutegravir (EMEA-001940-PIP01-16-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 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/0074/2017 issued on 17 March 2017,

Having regard to the application submitted by ViiV Healthcare UK Limited on 1 February 2018 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 27 April 2018, 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 lamivudine / dolutegravir, film-coated tablet, age appropriate oral solid dosage form, 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 ViiV Healthcare UK Limited, 980 Grest West Road,TW8 9GS - Brentford, United Kingdom.

EMA/PDCO/94448/2018 Corr
London, 27 April 2018

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

EMEA-001940-PIP01-16-M01

Scope of the application

Active substance(s):

Lamivudine / dolutegravir

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:

ViiV Healthcare UK Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ViiV Healthcare UK Limited submitted to the European Medicines Agency on 1 February 2018 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/0074/2017 issued on 17 March 2017.

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

The procedure started on 27 February 2018.

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 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 annex 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 2 years of age;
- film-coated tablet, age appropriate oral solid dosage form, 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

Adolescents (between 12 and 18 years old);

- Lamivudine (3TC) / dolutegravir (DTG) fix-dose-combination (FDC) is to be indicated for use as a 2-drug complete regimen for the treatment of ART-naïve adolescents above 12 to less than 18 years of age with plasma HIV-1 RNA less than 500,000 c/mL, or virologically suppressed adolescents, and without known viral drug resistance to either agent.

Children (above 2 to less than 12 years old);

- DTG/3TC FDC is to be indicated for use as a 2-drug complete regimen for the treatment of virologically suppressed children above 2 to less than 12 years of age without known viral drug resistance to either agent.

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)

Film-coated tablet

Age appropriate oral solid dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Paediatric formulation development

Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 2** Single dose, crossover, relative bioavailability study of DTG plus 3TC paediatric formulation as compared to approved DTG and 3TC formulations. **Study 3** Open-label, randomised, active controlled, non-inferiority study to evaluate the maintenance of Efficacy and Safety of dual therapy, DTG plus 3TC, in anti-retroviral therapy (ART)-experienced HIV-1-Infected Children, from 2 to less than 12 years of age who are virologically suppressed on their current anti-retroviral (ARV) regimen.
Extrapolation, modelling and simulation studies	1	**Study 4** Extrapolation of efficacy from adult to adolescents 12 to less than 18 years old weighing at least 40 kg.
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 December 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes