EMA/871152/2018

European Medicines Agency decision

P/0017/2019

of 3 January 2019

on the acceptance of a modification of an agreed paediatric investigation plan for dolutegravir (Tivicay), (EMEA-000409-PIP01-08-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/178/2009 issued on 7 September 2009, decision P/200/2010 issued on 27 October 2010, the decision P/0088/2012 issued on 29 May 2012 and the decision P/0061/2015 issued on 1 April 2015,

Having regard to the application submitted by ViiV Healthcare UK Ltd. on 10 August 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 16 November 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 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 dolutegravir (Tivicay), age appropriate formulation for oral use, film-coated tablets, 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 ViiV Healthcare UK Ltd., 980 Great West Road TW8 9GS - Brentford, Middlesex, United Kingdom.

EMA/PDCO/570919/2018
London, 16 November 2018

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

EMEA-000409-PIP01-08-M05

Scope of the application

Active substance(s):

Dolutegravir

Invented name:

Tivicay

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Age appropriate formulation for oral use

Film-coated tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK 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, ViiV Healthcare UK Ltd. submitted to the European Medicines Agency on 10 August 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/178/2009 issued on 7 September 2009, decision P/200/2010 issued on 27 October 2010, the decision P/0088/2012 issued on 29 May 2012 and the decision P/0061/2015 issued on 1 April 2015.

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

The procedure started on 18 September 2018.

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 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 (HIV) infection

The waiver applies to:

- the paediatric population from birth to less than 4 weeks of age;
- age appropriate formulation, tablet, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

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 1 infection

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

From 4 weeks to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablets

Age appropriate formulation for oral use

2.1.4. Studies

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age appropriate formulation for paediatric patients less than 6 years of age such as a powder for reconstitution, oral solution, oral granules, dispersible tablets or mini-tablets.
Non-clinical studies	2	**Study 2** Juvenile Toxicity Study in rats. **Study 3** Pre and Postnatal Toxicity Study in rats.

Clinical studies	1	**Study 4** Multicentre, open-label, non-comparative study to evaluate pharmacokinetics, safety, tolerability and antiviral activity of dolutegravir in HIV-1 infected infants, children and adolescents from 4 weeks to less than 18 years of age.
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 HIV infection

Authorised indication(s):

- Tivicay is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults, adolescents and children above 6 years of age.

Authorised pharmaceutical form(s):

Film-coated tablets

Authorised route(s) of administration:

Oral use