EMA/325187/2012

European Medicines Agency decision
P/0088/2012

of 29 May 2012

on the acceptance of a modification of an agreed paediatric investigation plan for dolutegravir (EMEA-000409-PIP01-08-M02) 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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on the acceptance of a modification of an agreed paediatric investigation plan for dolutegravir (EMEA-000409-PIP01-08-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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, and decision P/200/2010 issued on 27 October 2010,

Having regard to the application submitted by ViiV Healthcare UK Ltd. on 23 January 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 April 2012, 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 and on the granting of a waiver.

(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.

(3) It is therefore appropriate to adopt a decision on the granting of a waiver.

[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, age appropriate formulation for oral use, 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

A waiver for dolutegravir, age appropriate formulation for oral use, tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to ViiV Healthcare UK Ltd., 980 Great West Road, TW8 9GS Brentford, Middlesex, United Kingdom.

Done at London, 29 May 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/65208/2012

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

EMEA-000409-PIP01-08-M02

Scope of the application

Active substance(s):

Dolutegravir

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Age appropriate formulation for oral use

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK Ltd.

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 23 January 2012 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/178/2009 issued on 7 September 2009, and decision P/200/2010 issued on 27 October 2010.

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

The procedure started on 15 February 2012.

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Scope of the modification

Some measures and timelines of the PIP 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,
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 13 April 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Treatment of human immunodeficiency virus (HIV) infection

The waiver applies to:

- children from birth to less than 4 weeks of age;
- for dolutegravir age appropriate formulation for oral use
- and for dolutegravir tablet for 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)

1) 10 mg, 25 mg and 50 mg tablet for oral use.

2) An age appropriate formulation for oral use for the age group less than 6 years of age.

2.1.4. Studies

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

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes