EMA/793798/2014

European Medicines Agency decision

P/0009/2015

of 30 January 2015

on the acceptance of a modification of an agreed paediatric investigation plan for raltegravir (Isentress), (EMEA-000279-PIP01-08-M03) 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/95/2009 issued on 19 May 2009, the decision P/0099/2013 issued on 30 April 2013, and the decision P/0135/2014 issued on 11 June 2014,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 22 September 2014 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 12 December 2014, 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 raltegravir (Isentress), film-coated tablet, chewable tablet, granules for oral suspension, 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 Merck Sharp & Dohme (Europe), Inc., Lynx Binnenhof 5 Clos du Lynx, 1200 – Brussels, Belgium.

Done at London, 30 January 2015

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

EMA/PDCO/602677/2014

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

EMEA-000279-PIP01-08-M03

Scope of the application

Active substance(s):

Raltegravir

Invented name:

Isentress

Condition(s):

Treatment of Human Immunodeficiency Virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Chewable tablet

Granules for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe), Inc.

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, Merck Sharp & Dohme (Europe), Inc. submitted to the European Medicines Agency on 22 September 2014 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/95/2009 issued on 19 May 2009, the decision P/0099/2013 issued on 30 April 2013, and the decision P/0135/2014 issued on 11 June 2014.

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

The procedure started on 14 October 2014.

Scope of the modification

Some measures 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 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 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.

London, 12 December 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of Human Immunodeficiency Virus (HIV-1) infection

2.1.1. Indication targeted by the PIP

In combination with other anti-retroviral medicinal products for the 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

Chewable tablet

Granules for oral suspension

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	2	**Study 1:** Development of granules for oral suspension **Study 2:** Development of chewable tablets
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 3:** Open-label, non-comparative trial to evaluate pharmacokinetics, safety, tolerability, and anti-retroviral activity of raltegravir in HIV-1 infected treatment experienced children and adolescents from 6 months to less than 18 years of age. **Study 4:** Open-label, non-comparative trial to evaluate pharmacokinetics, safety and tolerability of raltegravir granules for oral suspension in neonates and infants less than 6 weeks of age (enrolled within 48 hours of birth) born to HIV infected mothers.

		Study 5: Open-label, non-comparative trial to evaluate the pharmacokinetics, safety, tolerability, and anti-retroviral activity of raltegravir with optimised background therapy (OBT) in HIV-1 infected treatment-naive children from 4 weeks to less than 6 months 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:	Yes
Date of completion of the paediatric investigation plan:	By June 2016
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):

1. Treatment of Human Immunodeficiency Virus (HIV-1) infection

Authorised indication(s):

- Isentress is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV 1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks

Authorised pharmaceutical form(s):

Film-coated tablets

Chewable tablets

Granules for oral suspension

Authorised route(s) of administration:

Oral use