

EMA/314181/2016

European Medicines Agency decision

P/0155/2016

of 15 June 2016

on the acceptance of a modification of an agreed paediatric investigation plan for raltegravir (Isentress), (EMA-000279-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 726/2004¹,

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 Agency²,

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, the decision P/0135/2014 issued on 11 June 2014, the decision P/0009/2015 issued on 30 January 2015, and the decision P/0187/2015 issued on 4 September 2015,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 27 January 2016 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 29 April 2016, 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 raltegravir (Isentress), film-coated tablet, chewable tablet, granules for oral suspension, 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 Merck Sharp & Dohme (Europe), Inc., Clos du Lynx 5, 1200 – Brussels, Belgium.

Done at London, 15 June 2016

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/88587/2016

London, 29 April 2016

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

EMA-000279-PIP01-08-M05

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



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 27 January 2016 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, the decision P/0135/2014 issued on 11 June 2014, the decision P/0009/2015 issued on 30 January 2015, and the decision P/0187/2015 issued on 4 September 2015.

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

The procedure started on 1 March 2016.

Scope of the modification

Some 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 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 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-naïve 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 March 2017
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