EMA/206647/2013

European Medicines Agency decision

P/0099/2013

of 30 April 2013

on the acceptance of a modification of an agreed paediatric investigation plan for raltegravir (ISENTRESS), (EMEA-000279-PIP01-08-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/0099/2013

of 30 April 2013

on the acceptance of a modification of an agreed paediatric investigation plan for raltegravir (ISENTRESS), (EMEA-000279-PIP01-08-M01) 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/95/2009 issued on 19 May 2009,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 17 December 2012 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 15 March 2013, 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, 1200 – Brussels, Belgium.

Done at London, 30 April 2013

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

EMA/PDCO/825515/2012

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

EMEA-000279-PIP01-08-M01

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 17 December 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/95/2009 issued on 19 May 2009.

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

The procedure started on 16 January 2013.

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 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.

London, 15 March 2013

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

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 measures	Description
Quality	2	Measure 1 - Development of granules for oral suspension Measure 2 - Development of chewable tablets
Non-clinical	0	Not applicable.
Clinical	3	Measure 3 – Multi-center, open-label, noncomparative study to evaluate the safety, tolerability, pharmacokinetics 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. Measure 4 – Open-label, noncomparative study to evaluate the safety and pharmacokinetics of raltegravir in neonates less than 6 weeks of age born to HIV infected mothers Measure 5 - Multi-center, open-label, noncomparative study to evaluate the safety, tolerability, pharmacokinetics and anti-retroviral activity of raltegravir in HIV-1 infected treatment-naive children from 4 weeks to less than 6 months of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2014
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 indications:

- ISENTRESS is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients.

Authorised pharmaceutical formulation(s):

Film-coated tablets

Authorised route(s) of administration:

Oral use