European Medicines Agency

Doc. Ref. EMEA/288499/2009
P/95/2009

EUROPEAN MEDICINES AGENCY DECISION

of 19 May 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for raltegravir (ISENTRESS) (EMEA-000279-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Merck Sharp & Dohme (Europe), Inc. on 23 May 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 3 April 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for raltegravir (ISENTRESS), film-coated tablet / chewable tablet / oral granules, oral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for raltegravir (ISENTRESS), film-coated tablet / chewable tablet / oral granules, oral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Merck Sharp & Dohme (Europe), Inc., Clos du Lynx 5, 1200, Brussels Belgium.

Done at London, 19 May 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/163007/2009
EMEA-000279-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL

Scope of the application

Active substance(s):
Raltegravir

(Invented) name:
ISENTRESS

Condition(s):
Human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):
Film-coated tablet
Chewable tablet
Oral granules

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 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted for agreement to the EMEA on 23 May 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 1 July 2008.

Supplementary information was provided by the applicant on 19 January 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation, and

- to grant a deferral in accordance with Article 21 of said Regulation.

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 agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 3 April 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

A. CONDITION(S)
Human immunodeficiency virus 1 infection

B. WAIVER

Not applicable

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Human immunodeficiency virus 1 infection

- **Proposed PIP indication**

In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection

- **Subset(s) of the paediatric population concerned by the paediatric development**

From birth to less than 18 years.

- **Formulation(s)**
  - Film-coated tablets
  - Ethylcellulose chewable tablet
  - Oral granules for suspension

- **Studies**

Area	Number of studies	Description
Quality	1	Oral Granules for Suspension, Oral use
Quality	1	Ethylcellulose Chewable tablet, Oral use
Clinical Study 1	1	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.
Clinical Study 2	1	Open-label, noncomparative study to evaluate the safety and pharmacokinetics of raltegravir in neonates less than 4 weeks of age born to HIV infected mothers
Clinical Study 3	1	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.

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By December 2014**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Packaging**	**Content (concentration)**	**Package size**
EU/1/07/436/001	ISENTRESS	400 mg	Film-coated tablets	Oral use	Bottle (HDPE)		60 tablets
EU/1/07/436/002	ISENTRESS	400 mg	Film-coated tablets	Oral use	Bottle (HDPE)		180 (3x60) tablets