EMA/700668/2011

European Medicines Agency decision

P/275/2011

of 11 November 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral for delamanid (EMEA-001113-PIP01-10) 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 agreement of a paediatric investigation plan and on the granting of a deferral for delamanid (EMEA-001113-PIP01-10) 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 application submitted by Otsuka Frankfurt Research Institute GmbH on 17 January 2011 under Article 16(1) of Regulation (EC) No 1901/2006 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 14 October 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing 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 delamanid, film-coated tablet, powder for oral suspension, 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 delamanid, film-coated tablet, powder for oral suspension, 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 Otsuka Frankfurt Research Institute GmbH, Hochhaus am Park, Grueneburgweg 102, 60323 Frankfurt am Main, Germany.

Done at London, 11 November 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMEA/PDCO/633061/2011

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001113-PIP01-10

Scope of the application

Active substance(s):

Delamanid

Condition(s):

Treatment of tuberculosis

Pharmaceutical form(s):

Film-coated tablet

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Otsuka Frankfurt Research Institute GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Otsuka Frankfurt Research Institute GmbH submitted for agreement to the European Medicines Agency on 17 January 2011 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 23 February 2011.

Supplementary information was provided by the applicant on 28 July 2011. The applicant proposed modifications to the paediatric investigation plan.

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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,
   - 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 European Medicines Agency, together with its annex(es) and appendix.

London, 14 October 2011

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 tuberculosis

2.1.1. Indication(s) targeted by the PIP

Treatment of multi drug resistant tuberculosis.

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.

Powder for oral suspension.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development of age-appropriate powder for oral suspension for children from birth to 5 years of age.
Non-clinical	1	**Study 2** 10-week juvenile repeat-dose toxicity and toxicokinetic study in rats.
Clinical	3	**Study 3** Open-label, randomised, single-centre, single-dose bioequivalence trial to compare delamanid suspension to delamanid 50 mg tablets in healthy adults. **Study 4** Open-label, uncontrolled, multicentre pharmacokinetics and safety trial of delamanid in children from birth to less than 18 years of age with MDR tuberculosis. **Study 5** Six (6)-month open-label extension trial of study 4 to evaluate long-term safety/tolerability, efficacy, and pharmacokinetics of delamanid in children from birth to less than 18 years of age with MDR tuberculosis.

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 April 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes