EMA/632684/2016

European Medicines Agency decision

P/0269/2016

of 7 October 2016

on the acceptance of a modification of an agreed paediatric investigation plan for delamanid (Deltyba), (EMEA-001113-PIP01-10-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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0269/2016

of 7 October 2016

on the acceptance of a modification of an agreed paediatric investigation plan for delamanid (Deltyba), (EMEA-001113-PIP01-10-M05) 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/275/2011 issued on 11 November 2011, the decision P/0241/2012 issued on 22 October 2012, the decision P/0296/2013 issued on 29 November 2013, the decision P/0281/2014 issued on 28 October 2014 and the decision P/0306/2015 issued on 21 December 2015,

Having regard to the application submitted by Otsuka Europe Development and Commercialisation Ltd. on 20 May 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 19 August 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 delamanid (Deltyba), film-coated tablet, dispersible tablet 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 Otsuka Europe Development and Commercialisation Ltd., Europa-Allee 52, 60327 - Frankfurt am Main, Germany.

EMA/PDCO/376905/2016
London, 19 August 2016

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

EMEA-001113-PIP01-10-M05

Scope of the application

Active substance(s):

Delamanid

Invented name:

Deltyba

Condition(s):

Treatment of multi drug resistant tuberculosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Dispersible tablet for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Otsuka Europe Development and Commercialisation Ltd.

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Otsuka Europe Development and Commercialisation Ltd. submitted to the European Medicines Agency on 20 May 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/275/2011 issued on 11 November 2011, the decision P/0241/2012 issued on 22 October 2012, the decision P/0296/2013 issued on 29 November 2013, the decision P/0281/2014 issued on 28 October 2014 and the decision P/0306/2015 issued on 21 December 2015.

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

The procedure started on 21 June 2016.

Scope of the modification

Some measures and 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 multi drug resistant 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

Dispersible tablet for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of age-appropriate dispersible tablet for oral suspension for children from birth to 5 years of age
Non-clinical studies	1	**Study 2** 10-week juvenile repeat-dose toxicity and toxicokinetic study in rats
Clinical studies	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 multi drug resistant (MDR) tuberculosis.

Area	Number of measures	Description
		Study 5 Six (6)-month open-label extension trial of study 4 with follow-up for at least 12 months after end of trial therapy 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.
Extrapolation, modelling and simulation studies		Not applicable.
Other studies		Not applicable.
Other measures		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 November 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes