EMA/392697/2019

European Medicines Agency decision

P/0271/2019

of 14 August 2019

on the acceptance of a modification of an agreed paediatric investigation plan for delamanid (Deltyba), (EMEA-001113-PIP01-10-M06) 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 726/2004[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, the decision P/0306/2015 issued on 21 December 2015 and the decision P/0269/2016 issued on 7 October 2016,

Having regard to the application submitted by Otsuka Pharmaceutical Development & Commercialisation Europe GmbH on 25 March 2019 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 28 June 2019, 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 Pharmaceutical Development & Commercialisation Europe GmbH, Europa-Allee 52, 60327 - Frankfurt am Main, Germany.

EMA/PDCO/225923/2019
Amsterdam, 28 June 2019

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

EMEA-001113-PIP01-10-M06

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 Pharmaceutical Development & Commercialisation Europe GmbH

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Otsuka Pharmaceutical Development & Commercialisation Europe GmbH submitted to the European Medicines Agency on 25 March 2019 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, the decision P/0306/2015 issued on 21 December 2015 and the decision P/0269/2016 issued on 7 October 2016.

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

The procedure started on 30 April 2019.

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 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. (OTS-PAED:RAT)
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. (OTS-BIOE) **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. (OTS-PAED-TB)

Area	Number of measures	Description
		Study 5 Six-months 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. (OTS-PAED-TB-EXTENSION)
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 March 2020
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):

Treatment of multi drug resistant tuberculosis

Authorised indication(s):

- Deltyba is indicated for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use