EMA/183759/2013

European Medicines Agency decision

P/0105/2013

of 30 April 2013

on the acceptance of a modification of an agreed paediatric investigation plan for bedaquiline (fumarate), (EMEA-000912-PIP01-10-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.

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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/55/2011 issued on 4 March 2011,

Having regard to the application submitted by Janssen Infectious Diseases BVBA 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 bedaquiline (fumarate), tablet, dispersible tablet, granules, 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 Janssen Infectious Diseases BVBA, Turnhoutseweg 30, B-2340 – Beerse, Belgium.

Done at London, 30 April 2013

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

EMA/PDCO/3741/2013 Corr

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

EMEA-000912-PIP01-10-M01

Scope of the application

Active substance(s):

Bedaquiline (fumarate)

Condition(s):

Treatment of multi-drug resistant tuberculosis

Pharmaceutical form(s):

Tablet

Dispersible tablet

Granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen Infectious Diseases BVBA

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen Infectious Diseases BVBA 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/55/2011 issued on 4 March 2011.

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

The procedure started on 16 January 2013.

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Scope of the modification

Modification of timelines following the development of an age appropriate formulation.

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.

   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 annex 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 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)

Tablet

Dispersible tablet

Granules

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1:** Development of an age appropriate formulation
Non-clinical	1	**Study 2:** Juvenile toxicity study in rats
Clinical	2	**Study 3:** Open-label, randomised, crossover study in healthy adult subjects to determine the relative bioavailability of TMC207 as tablet (for adults) to an age appropriate formulation and to investigate the food effect of the selected paediatric formulation. **Study 4:** Open-label, multicenter, single arm study to evaluate the pharmacokinetics, safety, tolerability and anti-mycobacterial activity of TMC207 in combination with a standard regimen of multi-drug resistant tuberculosis (MDR-TB) medications in children and adolescents aged from birth to less than 18 years of age who have been diagnosed with primarily pulmonary MDR-TB.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes