

EMA/254196/2011

European Medicines Agency decision

P/88/2011

of 8 April 2011

on the acceptance of a modification of an agreed paediatric investigation plan for boceprevir (EMA-000583-PIP01-09-M02) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/97/2010 issued on 04 June 2010 and the decision P/154/2010 issued on 27 August 2010,

Having regard to the application submitted by Merck Sharp & Dohme Ltd on 3 December 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 February 2011, in accordance with Article 22 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 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 boceprevir, granules, hard capsules, 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 Merck Sharp & Dohme Ltd, Hertford Road, EN11 9BU Hoddesdon, United Kingdom.

Done at London, 8 April 2011

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

EMA/PDCO/57885/2011

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000583-PIP01-09-M02

Scope of the application

Active substance(s):

Boceprevir

Condition(s):

Treatment of chronic hepatitis C

Pharmaceutical form(s):

Granules

Hard capsules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme Ltd submitted to the European Medicines Agency on 3 December 2010 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/97/2010 issued on 4 June 2010 and the decision P/154/2010 issued on 27 August 2010.

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

The procedure started on 22 December 2010.

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 Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver 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, 18 February 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

1.1. Condition: Treatment of chronic hepatitis C

The waiver applies to:

- The paediatric population from birth to less than 3 years of age,
- for hard capsules, granules, oral use,
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of chronic hepatitis C

2.1.1. Indication(s) targeted by the PIP

Treatment of children and adolescents from 3 years to less than 18 years of age with genotype 1 chronic HCV infection and without liver decompensation.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 3 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Hard capsules.

Granules.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Development of the granule formulation, including palatability testing, formulation selection and manufacture, bioavailability testing, and formulation development scale-up.
Non-clinical	3	Study 1: One-month thyroid hormone evaluation study of boceprevir in juvenile rats Study 2: Testicular toxicity and toxicokinetic study of oral (gavage) boceprevir in male neonatal rats Study 3: Thyroxine Clearance Study of Boceprevir in Juvenile Rats
Clinical	2	Study 4: PK Assessment Boceprevir in Paediatric Subjects With Chronic Hepatitis C Genotype 1 Study 5: Efficacy and Safety of Boceprevir in Combination with Peginterferon alfa-2b Plus Ribavirin in Paediatric Subjects With Chronic Hepatitis C

Area	Number of studies	Description
		Genotype 1

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:	Yes
Date of completion of the paediatric investigation plan:	By July 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes