EMA/85749/2013

European Medicines Agency decision

P/0068/2013

of 26 March 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for anacetrapib (EMEA-001100-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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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 Merck Sharp & Dohme (Europe), Inc. on 14 February 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 February 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.

(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.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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 anacetrapib, tablets, age-appropriate oral solid dosage form, 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 anacetrapib, tablets, age-appropriate oral solid dosage form, 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

A waiver for anacetrapib, tablets, age-appropriate oral solid dosage form, 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 4

This decision is addressed to Merck Sharp & Dohme (Europe), Inc., Clos Du Lynx 5, 1200 – Brussels, Belgium.

Done at London, 26 March 2013

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

EMA/PDCO/757298/2012

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

EMEA-001100-PIP01-10

Scope of the application

Active substance(s):

Anacetrapib

Condition(s):

Treatment of hypercholesterolaemia

Prevention of cardiovascular events in patients with hypercholesterolaemia

Pharmaceutical form(s):

Tablets

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe), Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted for agreement to the European Medicines Agency on 14 February 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 23 March 2011.

Supplementary information was provided by the applicant on 19 November 2012. The applicant proposed modifications to the paediatric investigation plan.

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;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, and Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 and appendix.

London, 8 February 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

1.1. Condition: treatment of hypercholesterolaemia

The waiver applies to:

- The paediatric population from birth to less than 6 years of age;
- for tablets, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition: prevention of cardiovascular events in patients with hypercholesterolaemia

- All subsets of the paediatric population from birth to less than 18 years of age;
- for tablets, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition: treatment of hypercholesterolaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of heterozygous familial hypercholesterolaemia, homozygous familial hypercholesterolaemia, primary non-familial hypercholesterolaemia and mixed dyslipidaemia.

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

From 6 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Tablets.

Age-appropriate oral solid dosage form.

2.1.4. Measures

Area	Number of measures	Description
Quality	1	**Measure 1** Development of age-appropriate oral solid dosage form for children from 6 years of age and older.

Non-clinical	0	Not applicable.
Clinical	4	**Measure 2** Open-label, single dose trial to evaluate pharmacokinetics, safety and tolerability of anacetrapib in children from 6 to less than 18 years of age with heterozygous familial hypercholesterolaemia. **Measure 3** Double-blind, randomised, multicentre, multiple dose, placebo controlled trial with 12 month open-label extension to evaluate safety and efficacy of anacetrapib, added to lipid-modifying therapy, in children from 10 to less than 18 years of age with heterozygous familial hypercholesterolaemia. **Measure 4** Double-blind, randomised, multicentre, multiple dose, placebo controlled trial with 12 month open-label extension to evaluate safety and efficacy of anacetrapib, added to lipid-modifying therapy, in children from 6 to less than 10 years of age with heterozygous familial hypercholesterolaemia. **Measure 5** Double-blind, randomised, multicentre, multiple dose, placebo controlled trial with 12 month open-label extension to evaluate safety and efficacy of anacetrapib, added to lipid-modifying therapy, in children from 6 to less than 18 years of age with homozygous familial hypercholesterolaemia or compound heterozygous familial hypercholesterolaemia.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes