EMA/578832/2015

European Medicines Agency decision

P/0206/2015

of 7 September 2015

on the acceptance of a modification of an agreed paediatric investigation plan for odanacatib (EMEA-001123-PIP01-11-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 726/2004[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/0127/2012 issued on 4 July 2012, and the decision P/0227/2013 issued on 23 September 2013,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 26 May 2015 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 14 August 2015, 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 odanacatib, tablet, 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 Merck Sharp & Dohme (Europe), Inc., Clos du Lynx 5 / Lynx Binnenhof 5, 1200 – Bruxelles, Belgium

Done at London, 7 September 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/392185/2015
London, 14 August 2015

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

EMEA-001123-PIP01-11-M02

Scope of the application

Active substance(s):

Odanacatib

Condition(s):

Treatment of osteoporosis

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe), Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted to the European Medicines Agency on 26 May 2015 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/0127/2012 issued on 4 July 2012, and the decision P/0227/2013 issued on 23 September 2013.

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

The procedure started on 16 June 2015.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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.

   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 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.

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

1.1. Condition: treatment of osteoporosis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 12 years of age and adolescents from 12 to less than 18 years of age with open growth plate/open epiphyses;
- for tablet, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: treatment of osteoporosis

2.1.1. Indication(s) targeted by the PIP

Treatment of glucocorticoid-induced osteoporosis.

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

From 12 years of age to less than 18 years of age with closed epiphyses.

2.1.3. Pharmaceutical form(s)

Tablet

2.1.4. Studies

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 1:** Double-blind, randomized, multicentre, single dose, multiple panel, placebo-controlled trial to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of odanacatib in adolescents from 12 to less than 18 years old with closed epiphyses and treated with glucocorticoid, and in young adults (Study PN066). **Study 2:** Double-blind, randomized, multicentre, multiple-dose, active controlled trial to evaluate efficacy, safety and tolerability of odanacatib in adolescents from 12 to less than 18 years old with closed

		epiphyses (and adults) and glucocorticoid-induced bone loss (Study PN052).
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2023
Deferral for one or more studies contained in the paediatric investigation plan:	Yes