EMA/299666/2014

European Medicines Agency decision

P/0150/2014

of 13 June 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for 5-(4,6-dimethyl-1H-benzimidazol-2-yl)-4-methyl-N-[3-(1-methyl-4-piperidinyl)propyl]-2-pyrimidinamine 2,3-dihydroxybutanedioate hydrate (1:0.5:4) (JNJ-38518168) (EMEA-001504-PIP01-13) 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 Janssen Cilag International NV on 4 July 2013 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 25 April 2014, 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 5-(4,6-dimethyl-1H-benzimidazol-2-yl)-4-methyl-N-[3-(1-methyl-4-piperidinyl)propyl]-2-pyrimidinamine 2,3-dihydroxybutanedioate hydrate (1:0.5:4) (JNJ-38518168), coated tablet, age appropriate oral 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 5-(4,6-dimethyl-1H-benzimidazol-2-yl)-4-methyl-N-[3-(1-methyl-4-piperidinyl)propyl]-2-pyrimidinamine 2,3-dihydroxybutanedioate hydrate (1:0.5:4) (JNJ-38518168), coated tablet, age appropriate oral 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 5-(4,6-dimethyl-1H-benzimidazol-2-yl)-4-methyl-N-[3-(1-methyl-4-piperidinyl)propyl]-2-pyrimidinamine 2,3-dihydroxybutanedioate hydrate (1:0.5:4) (JNJ-38518168), coated tablet, age appropriate oral 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 Janssen Cilag International NV, Turnhoutseweg 30, B2340 – Beerse, Belgium.

Done at London, 13 June 2014

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

EMA/PDCO/66697/2014

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

EMEA-001504-PIP01-13

Scope of the application

Active substance(s):

5-(4,6-dimethyl-1H-benzimidazol-2-yl)-4-methyl-N-[3-(1-methyl-4-piperidinyl)propyl]-2-pyrimidinamine 2,3-dihydroxybutanedioate hydrate (1:0.5:4) (JNJ-38518168)

Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

Pharmaceutical form(s):

Coated tablet

Age appropriate oral dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen Cilag International NV

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen Cilag International NV submitted for agreement to the European Medicines Agency on 4 July 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulationand a waiver under Article 13 of said Regulation.

The procedure started on 15 August 2013.

Supplementary information was provided by the applicant on 3 February 2014. The applicant proposed modifications to the paediatric investigation plan.

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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, 25 April 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

The waiver applies to:

- the paediatric population from birth to less than 1 years;
- for coated tablet and age appropriate dosage form, 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);

and

- the paediatric population from 1 year to less than 2 years;
- for coated tablet and age appropriate dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis

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

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Coated tablet

Age appropriate dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality – related studies	1	**Study 1** Development of age appropriate oral dosage form.

Non-clinical studies	2	**Study 2** Definitive juvenile toxicity study. **Study 3** Reprotox: (enhanced) pre- and postnatal development study.
Clinical studies	3	**Study 4** An open label study to evaluate the pharmacokinetics, safety and tolerability of JNJ 38518168 in children from 2 to less than 12 years old with juvenile idiopathic arthritis (JIA). **Study 5** A double-blind, multicentre, placebo controlled randomised-withdrawal study to evaluate the efficacy and safety of JNJ 38518168 in children from 2 to less than 18 years old with JIA. **Study 6** An open-label, single-arm study to assess the safety and efficacy of JNJ-38518168 in children from 2 to less than 18 years of age with refractory active anterior uveitis associated with juvenile idiopathic arthritis (JIA).
Extrapolation or modelling and simulation studies	1	**Study 7** Analysis of existing in house data on safety and efficacy of JNJ 38518168 in children with JIA.
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:	Yes.
Date of completion of the paediatric investigation plan:	By June 2026.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.