EMA/318383/2017

European Medicines Agency decision

P/0150/2017

of 9 June 2017

on the acceptance of a modification of an agreed paediatric investigation plan for sirukumab (EMEA-001043-PIP01-10-M03) 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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on the acceptance of a modification of an agreed paediatric investigation plan for sirukumab (EMEA-001043-PIP01-10-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/305/2011 issued on 20 December 2011, the decision P/0251/2014 issued on 30 September 2014 and the decision P/0020/2016 issued on 29 January 2016,

Having regard to the application submitted by Janssen-Cilag International N.V. on 30 January 2017 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 21 April 2017, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 20(1) of said Regulation 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 refusal of the changes to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan and refusal of the 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 sirukumab, solution for injection (in prefilled syringe), solution for injection (in prefilled pen), age-appropriate dosage form for parenteral use, subcutaneous 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

Changes to the deferral for sirukumab, solution for injection (in prefilled syringe), solution for injection (in prefilled pen), age-appropriate dosage form for parenteral use, subcutaneous use, are hereby refused in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 3

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, B2340 – Beerse, Belgium.

EMA/PDCO/81268/2017 Corr
London, 21 April 2017

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

EMEA-001043-PIP01-10-M03

Scope of the application

Active substance(s):

Sirukumab

Condition(s):

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

Pharmaceutical form(s):

Solution for injection (in prefilled syringe)

Solution for injection (in prefilled pen)

Age-appropriate dosage form for parenteral use

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Janssen-Cilag International N.V.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International N.V. submitted to the European Medicines Agency on 30 January 2017 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/305/2011 issued on 20 December 2011, the decision P/0251/2014 issued on 30 September 2014 and the decision P/0020/2016 issued on 29 January 2016.

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

The procedure started on 21 February 2017.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion;
   - to refuse changes to the deferral as it does not meet the grounds detailed in Article 20(1) of said Regulation.

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

The waiver applies to:

- the paediatric population from birth to less than 1 year;
- for solution for injection (in pre-filled syringe), solution for injection (in pre-filled pen), age-appropriate dosage form for parenteral use, subcutaneous 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 chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis 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 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection (in prefilled syringe)

Solution for injection (in prefilled pen)

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 5** Development of age-appropriate strength for small children
Non-clinical studies	1	**Study 1** Enhanced pre and postnatal development study

Clinical studies	3	**Study 2** A double-blind, parallel group study to evaluate pharmacokinetics, pharmacodynamics, safety and short term efficacy of sirukumab in patients with polyarticular and systemic JIA. **Study 3** A double-blind, randomised-withdrawal, multicentre study for evaluation of the safety and efficacy of sirukumab as a treatment for patients with polyarticular JIA (pJIA) **Study 4** A double-blind, randomised-withdrawal, multicentre study for evaluation of the safety and efficacy of sirukumab as a treatment for patients with systemic JIA (sJIA).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes