EMADOC-1700519818-1793192

European Medicines Agency decision

EMA/PE/0000183329

of 6 December 2024

on the of a modification of an agreed paediatric investigation plan for interleukin-23 receptor antagonist peptide (JNJ-77242113) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0323/2023 issued on 11 August 2023 and the decision P/0512/2023 issued on 29 December 2023,

Having regard to the application submitted by Janssen Cilag International on 5 July 2024 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 October 2024, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for interleukin-23 receptor antagonist peptide (JNJ-77242113), 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 Janssen Cilag International, Turnhoutseweg 30, 2340 - Beerse, Belgium.

EMADOC-1700519818-1620632
Amsterdam, 18 October 2024

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

EMA/PE/0000183329

Scope of the application

Active substance(s):

Interleukin-23 receptor antagonist peptide (JNJ-77242113)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of psoriasis

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen Cilag International

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen Cilag International submitted to the European Medicines Agency on 8 July 2024 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/0323/2023 issued on 11 August 2023 and the decision P/0512/2023 issued on 29 December 2023.

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

The procedure started on 19 August 2024.

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.

   The Paediatric Committee member of Norway 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 annexes 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 psoriasis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- film-coated tablet, age-appropriate formulation, 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 psoriasis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderate to severe plaque psoriasis in paediatric patients ≥6 years to <18 years of age who are candidates for systemic therapy

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)

Film-coated tablets

Age-appropriate formulation

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate oral formulation for paediatric use. **Study 2** Stability studies to support the dispersion of the tablet formulation.
Non-clinical studies	Not applicable
Clinical studies	**Study 3 (77242113PSO3001)** Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, efficacy of JNJ-77242113 in children from

	12 years to less than 18 years of age (and adults) with moderate to severe plaque psoriasis. **Study 4** Clinical trial to evaluate pharmacokinetics, safety, efficacy of JNJ-77242113 in children from 6 years to less than 12 years of age with moderate to severe plaque psoriasis.
Modelling and simulation studies	**Study 5** Modelling and simulation dose finding study
Other studies	Not applicable
Extrapolation plan	Study 3 and Study 4 are part of the extrapolation plan to extrapolate efficacy data from adults to adolescent patients from 12 to less than 18 years of age and from adults and adolescents to the paediatric population from 6 years to less than 12 years of age and adolescent patients with psoriasis with a body weight cut-off to be determined.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By April 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.