

EMA/330382/2023

European Medicines Agency decision P/0323/2023

of 11 August 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for interleukin-23 receptor antagonist peptide (EMEA-003301-PIP01-22) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Janssen-Cilag International NV on 8 August 2022 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 23 June 2023, in accordance with Article 17 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, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for interleukin-23 receptor antagonist peptide, film-coated tablet, age-appropriate formulation, 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 interleukin-23 receptor antagonist peptide, film-coated tablet, age-appropriate formulation, 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 interleukin-23 receptor antagonist peptide, film-coated tablet, age-appropriate formulation, 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, 30 Turnhoutseweg, B2340 – Beerse, Belgium.

EMA/PDCO/139585/2023
Amsterdam, 23 June 2023

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

EMA-003301-PIP01-22

Scope of the application

Active substance(s):

Interleukin-23 receptor antagonist peptide

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 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 8 August 2022 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 12 September 2022.

Supplementary information was provided by the applicant on 20 March 2023.

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 17(1) 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)(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 Paediatric Committee member of Norway 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 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 from 6 years to less than 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 adult 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