EMADOC-1700519818-1880424

European Medicines Agency decision

EMA/PE/0000230710

of 19 February 2025

on the acceptance of a modification of an agreed paediatric investigation plan for rocatinlimab 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 rocatinlimab 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 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/0320/2021 issued on 13 August 2021, the decision P/0168/2022 issued on 13 May 2022, the decision P/0017/2023 issued on 31 January 2023, and the decision P/0264/2023 issued on 14 July 2023,

Having regard to the application submitted by Amgen Europe B.V. on 17 October 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 31 January 2025, 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.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for rocatinlimab, 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 Amgen Europe B.V., Minervum 7061, 4817 ZK Breda, Netherlands.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

EMADOC-1700519818-1732546
Amsterdam, 28 January 2025

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

EMA/PE/0000230710

Scope of the application

Active substance(s):

Rocatinlimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Amgen Europe B.V.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Amgen Europe B.V. submitted to the European Medicines Agency on 17 October 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/0320/2021 issued on 13 August 2021, the decision P/0168/2022 issued on 13 May 2022, the decision P/0017/2023 issued on 31 January 2023, and the decision P/0264/2023 issued on 14 July 2023.

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

The procedure started on 25 November 2024.

Scope of the modification

Some measures and timelines 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 atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of atopic dermatitis

2.1.1. Indication targeted by the PIP

Treatment of moderate to severe atopic dermatitis (AD) with or without topical corticosteroids

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

From 6 months of age to less than 18 years of age

2.1.3. Pharmaceutical form

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Compatibility study of the solution for injection to ensure that the dosage preparation procedure and presentation is age appropriate
Non-clinical studies	**Study 2 (SBL303-238)** Enhanced pre- and postnatal development reproductive toxicity study
Clinical studies	**Study 3** Deleted during procedure EMEA-002886-PIP01-20-M01 **Study 4 (20210145)** A randomized, double-blind, placebo-controlled, parallel group two part study to investigate the efficacy and safety of rocatinlimab in adolescents age 12 years to less than 18 years of age with moderate to severe atopic dermatitis

	Study 5 A randomized, double-blind, placebo-controlled study to investigate the safety and efficacy of rocatinlimab in combination with topical corticosteroids (TCS) in subjects aged 6 years to less than 12 years with moderate to severe atopic dermatitis **Study 6** A two part open label dose finding (Part A) and randomised, double blind, placebo controlled study (Part B) to investigate pharmacokinetics (PK), pharmacodynamics (PD), safety and efficacy, of rocatinlimab in combination with topical corticosteroids (TCS) in children aged 6 months to less than 6 years, with moderate to severe atopic dermatitis
Extrapolation, modelling and simulation studies	**Study 7** Modelling and simulation study to evaluate the use of the product in the treatment of moderate to severe atopic dermatitis in children from 6 months to less than 18 years of age with moderate to severe atopic dermatitis
Other studies	Not applicable
Other measures	Not applicable

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 August 2035
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.