



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2406264

European Medicines Agency decision

EMA/PE/0000236886

of 10 September 2025

on the agreement of a paediatric investigation plan and on the granting of a waiver for baricitinib (Olumiant) 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 agreement of a paediatric investigation plan and on the granting of a waiver for baricitinib (Olumiant) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Eli Lilly Nederland B.V. on 22 November 2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting 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 July 2025, in accordance with Article 17 of Regulation (EC) No 1901/2006 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 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 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 baricitinib (Olumiant), 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 waiver for baricitinib (Olumiant), 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

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0069/2013 issued on 26 March 2013, including subsequent modifications thereof.

Article 4

This decision is addressed to Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, Netherlands.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2118257

Amsterdam, 25 July 2025

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

EMA/PE/0000236886

Scope of the application

Active substance(s):

Baricitinib

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of stage 3 type 1 diabetes mellitus

Pharmaceutical form(s):

Tablet

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eli Lilly Nederland B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eli Lilly Nederland B.V. submitted for agreement to the European Medicines Agency on 22 November 2024 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 2 January 2025.

Supplementary information was provided by the applicant on 21 April 2025. The applicant proposed modifications to the paediatric investigation plan.



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 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:

Prevention of stage 3 type 1 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- tablet, age-appropriate oral liquid 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:

Prevention of stage 3 type 1 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Delay of onset of Stage 3 type 1 diabetes in adult and paediatric patients aged 1 year and older with Stage 1b/2 type 1 diabetes (T1D).

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

From 1 year of age to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Tablet

Age-appropriate oral liquid dosage form

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (I4V-MC-JAJJ) Double-blind, randomised, placebo-controlled study to evaluate pharmacokinetics, safety and efficacy of baricitinib compared to placebo in children from 1 year of age to less than 18 years of age (and in adults) with stage 1b and stage 2 type 1 diabetes mellitus.

Modelling and simulation analyses	Study 2 Modelling and simulation analysis to characterize the baricitinib pharmacokinetics (PK) in adult and paediatric patients with T1D, confirm or modify the paediatric posology, and explore any relationship between exposure and pharmacodynamic endpoints of beta-cell function.
Other studies	Not applicable
Extrapolation plan	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 March 2034
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

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

Authorised indication(s):

- Treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Baricitinib may be used as monotherapy or in combination with methotrexate.
 - Invented name(s): Olumiant
 - Authorised pharmaceutical form(s): Film-coated tablet (tablet)
 - Authorised route(s) of administration: Oral use
 - Authorised via centralised procedure
- Treatment of active juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs:
 - Polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive [RF+] or negative [RF-], extended oligoarticular),
 - Enthesitis-related arthritis, and
 - Juvenile psoriatic arthritis.

Baricitinib may be used as monotherapy or in combination with methotrexate

- Invented name(s): Olumiant
- Authorised pharmaceutical form(s): Film-coated tablet (tablet)
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure

2. Treatment of atopic dermatitis

Authorised indication(s):

- Treatment of moderate to severe atopic dermatitis in adult and paediatric patients 2 years of age and older who are candidates for systemic therapy.
 - Invented name(s): Olumiant
 - Authorised pharmaceutical form(s): Film-coated tablet (tablet)
 - Authorised route(s) of administration: Oral use
 - Authorised via centralised procedure

3. Treatment of alopecia areata

Authorised indication(s):

- Treatment of severe alopecia areata in adult patients.
 - Invented name(s): Olumiant
 - Authorised pharmaceutical form(s): Film-coated tablet (tablet)
 - Authorised route(s) of administration: Oral use
 - Authorised via centralised procedure