EMA/84139/2023

European Medicines Agency decision

P/0063/2023

of 3 March 2023

on the acceptance of a modification of an agreed paediatric investigation plan for baricitinib (Olumiant), (EMEA-001220-PIP01-11-M07) 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/0069/2013 issued on 26 March 2013, the decision P/0192/2016 issued on 15 July 2016, the decision P/0026/2018 issued on 30 January 2018, the decision P/0157/2018 issued on 15 June 2018, the decision P/0165/2019 issued on 15 May 2019 and the decision P/0004/2022 issued on 31 January 2022,

Having regard to the application submitted by Eli Lilly and Company Limited on 14 October 2022 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 20 January 2023, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 baricitinib (Olumiant), oral suspension, film-coated tablet, oral use, including changes to the deferral, 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 Eli Lilly and Company Limited, 8 Arlington Square West, Downshire Way, RG12 1PU – Bracknell, United Kingdom.

EMA/PDCO/868785/2022
Amsterdam, 20 January 2023

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

EMEA-001220-PIP01-11-M07

Scope of the application

Active substance(s):

Baricitinib

Invented name and authorisation status:

See Annex II

Condition(s):

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

Pharmaceutical form(s):

Oral suspension

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eli Lilly and Company Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Limited submitted to the European Medicines Agency on 14 October 2022 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/0069/2013 issued on 26 March 2013, the decision P/0192/2016 issued on 15 July 2016, the decision P/0026/2018 issued on 30 January 2018, the decision P/0157/2018 issued on 15 June 2018, the decision P/0165/2019 issued on 15 May 2019 and the decision P/0004/2022 issued on 31 January 2022.

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

The procedure started on 21 November 2022.

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 and to the deferral 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 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;
- oral suspension, film-coated tablet, oral 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

Treatment of JIA-associated uveitis

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)

Oral suspension

Film-coated tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate liquid oral formulation
Non-clinical studies	2	**Study 2** Pre- and postnatal development study in rats **Study 3** Juvenile toxicology study in rats
Clinical studies	3	**Study 4** (I4V-MC-JAHV)

		Double-blind, randomised, withdrawal, placebo-controlled study to evaluate safety and efficacy of baricitinib in children from 2 years to less than 18 years of age with juvenile idiopathic arthritis (JIA) **Study 5** (I4V-MC-JAHU) Double-blind, randomised, withdrawal, placebo-controlled study to evaluate safety, efficacy and pharmacokinetics of baricitinib in children from 1 year to less than 18 years of age with systemic juvenile idiopathic arthritis (sJIA) **Study 6** (I4V-MC-JAHW) Open-label, active controlled trial to evaluate safety and efficacy of baricitinib compared to adalimumab in children from 2 years to less than 18 years of age with active JIA-associated uveitis or chronic anterior antinuclear antibody-positive (ANA-positive) uveitis without systemic features
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

The date of completion of the paediatric investigation plan corresponds to the timeline for completion of the latest measure(s) reported below.

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 September 2025
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:

Condition(s) and authorised indication(s):

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

2. Treatment of atopic dermatitis

3. Treatment of alopecia areata

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. Olumiant may be used as monotherapy or in combination with methotrexate.
- Treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy.
- Treatment of severe alopecia areata in adult patients.

Authorised pharmaceutical form(s):

Film-coated tablet (tablet)

Authorised route(s) of administration:

Oral use

Invented name: Olumiant