EMA/697754/2022

European Medicines Agency decision

P/0364/2022

of 9 September 2022

on the acceptance of a modification of an agreed paediatric investigation plan for baricitinib (Olumiant), (EMEA-001220-PIP07-20-M01) 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/0062/2021 issued on 5 February 2021,

Having regard to the application submitted by Eli Lilly and Company Limited on 21 April 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 22 July 2022, 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), film-coated tablet, age-appropriate oral liquid dosage form, 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 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 and in the decision P/0291/2018 issued on 12 September 2018, including subsequent modifications thereof.

Article 3

This decision is addressed to Eli Lilly and Company Limited, 8 Arlington Square West, RG12 1PU – Bracknell, United Kingdom.

EMA/PDCO/242903/2022
Amsterdam, 22 July 2022

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

EMEA-001220-PIP07-20-M01

Scope of the application

Active substance(s):

Baricitinib

Invented name:

Olumiant

Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eli Lilly and Company Limited

Information about the authorised medicinal product:

See Annex II

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 21 April 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/0062/2021 issued on 5 February 2021.

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

The procedure started on 23 May 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 coronavirus disease 2019 (COVID-19)

The waiver applies to:

- all subsets of the paediatric population from birth to less than 1 year of age;
- film-coated tablet, age-appropriate liquid oral formulation, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Treatment of coronavirus disease 2019 (COVID-19) in paediatric subjects from 1 year to less than 18 years of age requiring supplemental oxygen

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

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate liquid oral formulation

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Development of an age-appropriate oral liquid pharmaceutical form for baricitinib
Non-clinical studies	Not applicable
Clinical studies	**Study 2** Open-label, single-arm study to evaluate the pharmacokinetics and safety of baricitinib and to provide PK/PD data to support the extrapolation of efficacy from adults to paediatric patients from 1 year to less than 18 years of age with confirmed COVID-19

Extrapolation, modelling and simulation studies	**Study 3** Modelling and simulation study to determine and confirm a paediatric dose for baricitinib in paediatric patients from 1 year to less than 18 years of age with confirmed COVID-19 that should achieve an exposure equivalent to that observed in adults **Study 4** Extrapolation study to support efficacy assumptions for baricitinib in the paediatric population from 1 year to less than 18 years of age with COVID-19 from adult patients with confirmed COVID-19
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:	January 2024.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of chronic idiopathic arthritis

Authorised indication(s):

- Olumiant is indicated for the 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

2. Treatment of atopic dermatitis

Authorised indication(s):

- Olumiant is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy

Authorised pharmaceutical form(s):

Film-coated tablet (tablet)

Authorised route(s) of administration:

Oral use