EMA/142543/2024

European Medicines Agency decision

P/0130/2024

of 11 April 2024

on the acceptance of a modification of an agreed paediatric investigation plan for mirikizumab (Omvoh), (EMEA-002208-PIP01-17-M04) 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/0283/2018 issued on 12 September 2018, the decision P/0130/2020 issued on 15 April 2020 and the decision P/0088/2022 issued on 11 March 2022 and the decision P/0534/2023 issued on 29 December 2023.

Having regard to the application submitted by Eli Lilly and Company on 19 January 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 22 March 2024, 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.

[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 mirikizumab (Omvoh), concentrate for solution for infusion, solution for injection, intravenous use, subcutaneous use, 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/0129/2024 issued on 11 April 2024, including subsequent modifications thereof.

Article 3

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

EMA/PDCO/48750/2024
Amsterdam, 22 March 2024

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

EMEA-002208-PIP01-17-M04

Scope of the application

Active substance(s):

Mirikizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of Crohn's disease

Pharmaceutical form(s):

Concentrate for solution for infusion

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Eli Lilly and Company

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company submitted to the European Medicines Agency on 19 January 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/0283/2018 issued on 12 September 2018, the decision P/0130/2020 issued on 15 April 2020 and the decision P/0088/2022 issued on 11 March 2022 and the decision P/0534/2023 issued on 29 December 2023.

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

The procedure started on 26 February 2024.

Scope of the modification

Amendment of the scope of the Paediatric Investigation Plan to exclude another condition(s).

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 Crohn's disease

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- concentrate for solution for infusion, solution for injection, intravenous use, subcutaneous 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 Crohn's disease (CD)

2.1.1. Indication(s) targeted by the PIP

Treatment of Crohn's disease

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	***Study 1*** Development of pre-filled syringe presentations for subcutaneous use
Non-clinical studies	***Study 2*** Pre- and postnatal development study in cynomolgus monkeys (20102344)
Clinical studies	**Study 3** Multicentre study to evaluate safety, tolerability, pharmacokinetics, and efficacy of mirikizumab in children and adolescents from 2 to less than 18 years of age with Crohn's disease. (I6T-MC-AMAY)

Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

2.2. Condition:

Treatment of psoriasis

This condition and study 3 has been delted as part of modification EMEA-002208-PIP01-17-M02.

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 July 2027
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 ulcerative colitis

Authorised indication(s):

- Omvoh is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.
- Invented name(s): Omvoh
- Authorised pharmaceutical form(s): Concentrate for solution for infusion, solution for injection in pre-filled syringe, solution for injection in pre-filled pen
- Authorised route(s) of administration: intravenous use, subcutaneous use
- Authorised via centralised procedure