EMADOC-1700519818-1855569

European Medicines Agency decision

EMA/PE/0000232930

of 28 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for mirikizumab (Omvoh) 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 mirikizumab (Omvoh) 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/0129/2024 issued on 11 April 2024,

Having regard to the application submitted by Eli Lilly And Company Limited on 11/10/2024 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 13 December 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), 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.

EMADOC-1700519818-1731492
Amsterdam, 13 December 2024

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

EMA/PE/0000232930

Scope of the application

Active substance(s):

Mirikizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ulcerative colitis

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 11 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/0129/2024 issued on 11 April 2024.

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

The procedure started on 25 November 2024.

Scope of the modification

The pharmaceutical form was amended.

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 members of Liechtenstein and Norway agree 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 ulcerative colitis

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 ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of ulcerative colitis

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*** (study identical to study 1 in EMEA-002208-PIP01-17 and modifications thereof) Development of an age appropriate paediatric pharmaceutical form for parenteral use
Non-clinical studies	***Study 2*** (study identical to study 1 in EMEA-002208-PIP01-17 and modifications thereof) Pre- and postnatal development study in cynomolgus monkeys. (20102344)
Clinical studies	**Study 3** Multicentre study to evaluate safety, tolerability, and efficacy of mirikizumab in children and adolescents from 2

	years to less than 18 years of age with ulcerative colitis. (I6T-MC-AMBA) **Study 4** Multicentre, open-label pharmacokinetic (PK) study of mirikizumab in children and adolescents from 2 years to less than 18 years of age with ulcerative colitis. (I6T-MC-AMBU)
Extrapolation, modelling and simulation studies	Not applicable.
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:	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 of ulcerative colitis (Commission Decision dated 26 May 2023)

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 300 mg concentrate for solution for infusion
  - Omvoh 100 mg solution for injection in pre-filled syringe
  - Omvoh 100 mg solution for injection in pre-filled pen
- Authorised pharmaceutical form(s):
  - Concentrate for solution for infusion (sterile concentrate)
  - Solution for injection (injection)
- Authorised route(s) of administration:
  - 300 mg sterile concentrate mirikizumab for IV use after dilution
  - Omvoh 100 mg injection mirikizumab SC
- Authorised via centralised procedure