EMA/132148/2020

European Medicines Agency decision

P/0130/2020

of 15 April 2020

on the acceptance of a modification of an agreed paediatric investigation plan for mirikizumab (EMEA-002208-PIP01-17-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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on the acceptance of a modification of an agreed paediatric investigation plan for mirikizumab (EMEA-002208-PIP01-17-M01) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary 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,

Having regard to the application submitted by Eli Lilly and Company on 28 November 2019 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 28 February 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for mirikizumab, 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 is addressed to Eli Lilly and Company Erl Wood Manor, Sunninghill Road, GU20 6PH – Windlesham, United Kingdom.

EMA/PDCO/691893/2019
Amsterdam, 28 February 2020

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

EMEA-002208-PIP01-17-M01

Scope of the application

Active substance(s):

Mirikizumab

Condition(s):

Treatment of psoriasis

Treatment of ulcerative colitis

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 28 November 2019 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 6 January 2020.

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 in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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 annex 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 psoriasis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- concentrate for solution for infusion, solution for injection in pre-filled syringe, intravenous use, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. 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 in pre-filled syringe, intravenous use, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.3. 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 in pre-filled syringe, 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 psoriasis

2.1.1. Indication(s) targeted by the PIP

Treatment of plaque psoriasis

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection (in pre-filled syringe)

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of pre-filled syringe presentations for subcutaneous use.
Non-clinical studies	1	**Study 2** Pre- and postnatal development study in cynomolgus monkeys. (20102344)
Clinical studies	1	**Study 3** Multicentre study to evaluate safety, tolerability, pharmacokinetics, and efficacy of mirikizumab in children and adolescents from 6 to less than 18 years of age with plaque psoriasis. (I6T-MC-AMAW)
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of ulcerative colitis

2.2.1. Indication(s) targeted by the PIP

Treatment of ulcerative colitis

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

From 2 to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Concentrate for solution for infusion

Solution for injection (in pre-filled syringe)

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	1	***Study 1*** *The same as for "Treatment of psoriasis"*
Non-clinical studies	1	***Study 2*** *The same as for "Treatment of psoriasis"*
Clinical studies	2	**Study 4** Multicentre study to evaluate safety, tolerability, and efficacy of mirikizumab in children and adolescents from 2 to less than 18 years of age with ulcerative colitis. (I6T-MC-AMBA) **Study 7** 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. (AMBU)
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.3. Condition:

Treatment of Crohn's disease (CD)

2.3.1. Indication(s) targeted by the PIP

Treatment of Crohn's disease

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

From 2 to less than 18 years of age

2.3.3. Pharmaceutical form(s)

Concentrate for solution for infusion

Solution for injection (in pre-filled syringe)

2.3.4. Measures

Area	Number of measures	Description
Quality-related studies	1	***Study 1*** *The same as for "Treatment of psoriasis"*
Non-clinical studies	1	***Study 2*** *The same as for "treatment of psoriasis"*
Clinical studies	2	**Study 5** Multicentre study to evaluate safety, tolerability, pharmacokinetics, and efficacy of mirikizumab in children and adolescents from 2 to less than 15 years of age with Crohn's disease. (I6T-MC-AMAY) **Study 6** An open label addendum to the AMAM adult study to assess efficacy and safety of mirikizumab in the induction and maintenance of remission in adolescents (15 to <18 years of age) with Crohn's disease. (I6T-MC-AMAM addendum for adolescents)
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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