EMA/31976/2021

European Medicines Agency decision

P/0056/2021

of 29 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for lasmiditan (EMEA-002166-PIP01-17-M05) 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 lasmiditan (EMEA-002166-PIP01-17-M05) 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/0167/2018 issued on 15 June 2018, the decision P/0358/2018 issued on 7 December 2018, the decision P/0291/2019 issued on 14 August 2019 and the decision P/0299/2020 issued on 12 August 2020,

Having regard to the application submitted by Eli Lilly and Company Limited on 10 September 2020 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 11 December 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 lasmiditan, tablet, orodispersible tablet, oral 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 Limited, 8 Arlington Square West, Downshire Way, RG12 1PU - Bracknell, United Kingdom.

EMA/PDCO/523578/2020 Corr
Amsterdam, 11 December 2020

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

EMEA-002166-PIP01-17-M05

Scope of the application

Active substance(s):

Lasmiditan

Condition(s):

Treatment of migraine headaches

Pharmaceutical form(s):

Tablet

Orodispersible 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 10 September 2020 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/0167/2018 issued on 15 June 2018, the decision P/0358/2018 issued on 7 December 2018, the decision P/0291/2019 issued on 14 August 2019 and the decision P/0299/2020 issued on 12 August 2020.

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

The procedure started on 13 October 2020.

Scope of the modification

Some measures 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 migraine headaches

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet, orodispersible tablet, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Treatment of migraine headaches

2.1.1. Indication(s) targeted by the PIP

Acute treatment of migraine with and without aura

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Orodispersible tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a bioequivalent orodispersible tablet with effective taste mask
Non-clinical studies	1	**Study 2** Definitive juvenile toxicity study in rats (353404)
Clinical studies	3	**Study 3** Open-label, single dose pharmacokinetic and tolerability study of lasmiditan in paediatric subjects from 6 years to less than 18 years of age with a history of migraine headache (H8H-MC-LAHX)

		Study 4 Randomized, double-blind, placebo-controlled, parallel-group study to assess efficacy and safety of lasmiditan in paediatric subjects from 6 years to less than 18 years of age with migraine (H8H-MC-LAHV) **Study 5** Open label, long-term safety study of lasmiditan in paediatric subjects from 6 years to less than 18 years of age with migraine with or without aura who have completed Study 3 or 4 (H8H-MC-LAHW)
Extrapolation, modelling and simulation studies	1	**Study 6** Modelling and simulation study for initial paediatric dose finding
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 October 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes