EMA/173699/2019

# European Medicines Agency decision

P/0111/2019

of 22 March 2019

on the acceptance of a modification of an agreed paediatric investigation plan for galcanezumab (Emgality), (EMEA-001860-PIP03-16-M02) 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 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/0341/2016 issued on 5 December 2016 and the decision P/0137/2018 issued on 7 May 2018,

Having regard to the application submitted by Eli Lilly and Company Limited on 29 October 2018 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 1 February 2019, 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 galcanezumab (Emgality), solution for injection, 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 Limited, Lilly Research Centre, Erl Wood Manor, Sunninghill Road, GU20 6PH - Windlesham, Surrey, United Kingdom.

EMA/PDCO/798096/2018
London, 1 February 2019

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

EMEA-001860-PIP03-16-M02

## Scope of the application

**Active substance(s):**

Galcanezumab

**Invented name:**

Emgality

**Condition(s):**

Prevention of migraine headaches

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Subcutaneous use

**Name/corporate name of the PIP applicant:**

Eli Lilly and Company Limited

**Information about the authorised medicinal product:**

See Annex II

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## 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 29 October 2018 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/0341/2016 issued on 5 December 2016 and the decision P/0137/2018 issued on 7 May 2018.

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

The procedure started on 4 December 2018.

## 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 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*

Prevention of migraine headaches

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- solution for injection, 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*

Prevention of migraine headaches

### 2.1.1. Indication(s) targeted by the PIP

Prophylactic treatment of migraine headache

### 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

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 0 | Not applicable |
| Non-clinical studies | 3 | **Study 1**<br>Enhanced pre- and postnatal development reproductive toxicity study in rats<br>**Study 2**<br>Definitive juvenile toxicity study in rats<br>**Study 3**<br>Fertility and early embryonic development reproductive toxicity study |

| | | |
|---|---|---|
| Clinical studies | 2 | **Study 4**<br><br>Randomised double-blind placebo-controlled study trial to evaluate pharmacokinetics, safety, efficacy, of galcanezumab in children from 6 to less than 18 years of age with episodic migraine (I5Q-MC-CGAS)<br><br>**Study 5**<br><br>Randomised double-blind placebo-controlled study trial to evaluate, safety, efficacy, of galcanezumab in paediatric patients from 12 to less than 18 years of age with chronic migraine |
| Extrapolation, modelling and simulation studies | 1 | **Study 6**<br><br>Modelling and simulation study, to support initial dose determination of galcanezumab in children from 6 to less than 18 years of age with migraine and further paediatric development |
| 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: | Yes |
| Date of completion of the paediatric investigation plan: | By February 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. Prevention of migraine

Authorised indication(s):

- Emgality is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

## Authorised pharmaceutical form(s):

Solution for injection

## Authorised route(s) of administration:

Subcutaneous use