EMA/666633/2017

European Medicines Agency decision

P/0308/2017

of 31 October 2017

on the acceptance of a modification of an agreed paediatric investigation plan for fremanezumab (EMEA-001877-PIP01-15-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 fremanezumab (EMEA-001877-PIP01-15-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/0301/2016 issued on 4 November 2016,

Having regard to the application submitted by Teva GmbH on 21 June 2017 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 15 September 2017, 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 fremanezumab, 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 Teva GmbH, Graf-Arco-Str. 3, 89079 – Ulm, Germany.

EMA/PDCO/436063/2017 Corr
London, 15 September 2017

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

EMEA-001877-PIP01-15-M01

Scope of the application

Active substance(s):

Fremanezumab

Condition(s):

Prevention of migraine headaches

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Teva GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Teva GmbH submitted to the European Medicines Agency on 21 June 2017 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/0301/2016 issued on 4 November 2016.

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

The procedure started on 18 July 2017.

Scope of the modification

Timelines of non-clinical studies the Paediatric Investigation Plan have been modified.

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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

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

Prophylaxis of headache in children aged 6 to 18 years with episodic and chronic migraine

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	
Non-clinical studies	2	**Study 1** Reproductive toxicity and post-natal development study. **Study 2** Definitive juvenile toxicity study.
Clinical studies	4	**Study 3** Pharmacokinetic and safety study in paediatric patients from 6 to less than 12 years of age following a single subcutaneous dose of fremanezumab.

		Study 4 Efficacy and safety, placebo controlled study of fremanezumab in paediatric patients from 6 to less than 18 years of age with episodic migraine (EM). **Study 5** Efficacy and safety, placebo controlled study of fremanezumab in paediatric patients from 6 to less than 18 years of age with Chronic Migraine (CM). **Study 6** Long-term, safety, tolerability and efficacy open-label single arm study of fremanezumab in paediatric patients from 6 to less than 18 years of age with history of migraine (CM or EM) with biomarker analysis who participated to Study 4 and 5.
Extrapolation, modelling and simulation studies	3	**Study 7** Modelling and simulation dose-finding study based on a two-compartment model with allometric weight scaling with data from adult patients with EM and CM. **Study 8** Modelling and simulation dose-finding study based on a two-compartment model with allometric weight scaling with data from paediatric pharmacokinetic study 3. **Study 9** Modelling and simulation inferential study including a comprehensive evaluation of the effect of covariates on PK and exposure-response parameters pooling all available paediatric and adult data.
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 November 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes