EMA/501874/2008

European Medicines Agency decision

P/0301/2016

of 4 November 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal TEV-48125 heavy chain), disulphide with human-Mus musculus monoclonal TEV-48125 light chain, dimer (TEV-48125) (EMEA-001877-PIP01-15) 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 application submitted by Teva Pharma GmbH on 23 November 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 September 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal TEV-48125 heavy chain), disulphide with human-Mus musculus monoclonal TEV-48125 light chain, dimer (TEV-48125), solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal TEV-48125 heavy chain), disulphide with human-Mus musculus monoclonal TEV-48125 light chain, dimer (TEV-48125), solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal TEV-48125 heavy chain), disulphide with human-Mus musculus monoclonal TEV-48125 light chain, dimer (TEV-48125), solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Teva Pharma GmbH, Waldeckerstr. 7, 64546 - Mörfelden-Walldorf, Germany.

EMA/PDCO/481405/2016
London, 16 September 2016

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001877-PIP01-15

Scope of the application

Active substance(s):

Immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal TEV-48125 heavy chain), disulphide with human-Mus musculus monoclonal TEV-48125 light chain, dimer (TEV-48125)

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 Pharma GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Teva Pharma GmbH submitted for agreement to the European Medicines Agency on 23 November 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 4 January 2016.

Supplementary information was provided by the applicant on 27 June 2016. The applicant proposed modifications to the paediatric investigation plan.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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;
- 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 TEV-48125.

		Study 4 Efficacy and safety, placebo controlled study of TEV-48125 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 TEV-48125 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 TEV-48125 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