EMA/141779/2018

European Medicines Agency decision

P/0124/2018

of 11 April 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for fevipiprant (EMEA-001315-PIP02-16) 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 Novartis EuroPharm Ltd. on 12 May 2016 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 23 February 2018, in accordance with Article 17 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 fevipiprant, tablet, chewable tablet, age-appropriate oral liquid dosage form, oral 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 fevipiprant, tablet, chewable tablet, age-appropriate oral liquid dosage form, oral 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 fevipiprant, tablet, chewable tablet, age-appropriate oral liquid dosage form, oral 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 Novartis EuroPharm Ltd., FRIMLEY BUSINESS PARK, GU16 7SR – Camberley, United Kingdom.

EMA/PDCO/843293/2017
London, 23 February 2018

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

EMEA-001315-PIP02-16

Scope of the application

Active substance(s):

Fevipiprant

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Tablet

Chewable tablet

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis EuroPharm Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis EuroPharm Ltd. submitted for agreement to the European Medicines Agency on 12 May 2016 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 21 June 2016.

Supplementary information was provided by the applicant on 11 December 2017. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) 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:

Treatment of asthma

The waiver applies to:

- the paediatric population from birth to less than 1 year;
- tablet, chewable tablet, age-appropriate oral liquid dosage form, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Maintenance treatment of uncontrolled persistent asthma in children 1 to less than 18 years old

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Chewable tablet

Age-appropriate oral liquid dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1:** Development of a chewable tablet **Study 2:** Development of an age-appropriate oral liquid dosage form
Non-clinical studies	1	**Study 3:** Definitive juvenile toxicity study in Rats

Clinical studies	8	**Study 4** Randomised, double-blind, parallel-group, placebo-controlled study over 52 weeks to assess the efficacy and safety of fevipiprant when added to existing asthma therapy in adolescents (and adults) with uncontrolled severe asthma. (CQAW0039A2307/CQAW039A2314) **Study 5** Bioequivalence/comparative bioavailability to determine the bioavailability study of two different paediatric fevipiprant oral formulations relative to film-coated tablets as well as the relative bioavailability of the two paediatric formulations (CQAW039A2114) **Study 6** Open-label, pharmacokinetic, safety and tolerability study of fevipiprant in paediatric patients aged 6 to <12 years. (CQAW039B2201) **Study 7** Open-label, pharmacokinetic, safety and tolerability study of fevipiprant in paediatric patients aged 1 to <6 years. (CQAW039B2102) **Study 8** Randomised, double-blind, parallel-group, placebo-controlled study to determine efficacy and safety of once daily fevipiprant, compared with placebo in children 6 to <12 years with uncontrolled moderate to severe persistent asthma. (CQAW039B2302) **Study 9** Randomised, double-blind, parallel-group, placebo-controlled study to determine efficacy and safety of once daily fevipiprant, compared with placebo in children 1 to <6 years with uncontrolled moderate to severe persistent asthma. (CQAW039B2301) **Study 10** Randomised, double-blind double-dummy, parallel group study to demonstrate the non-inferiority of once-daily fevipiprant compared with low-dose inhaled corticosteroids (ICS) in children 1 to <6 years with uncontrolled mild persistent asthma. (CQAW039B2304) **Study 11** Randomised, double-blind double-dummy, parallel group study to demonstrate the non-inferiority of once-daily fevipiprant compared with low-dose inhaled corticosteroids (ICS) in children and adolescents 6 to <18 years with uncontrolled mild persistent asthma. (CQAW039B2305)

Extrapolation, modelling and simulation studies	2	**Study 12** Dose finding population PK modelling and simulation study. **Study 13** Dose finding physiology based PK modelling and simulation study.
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 June 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes