EMA/793125/2017

European Medicines Agency decision

P/0384/2017

of 19 December 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for budesonide / glycopyrronium bromide / formoterol (fumarate) (EMEA-002063-PIP01-16) 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 Pearl Therapeutics, Inc. on 12 September 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 10 November 2017, 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 budesonide / glycopyrronium bromide / formoterol (fumarate), pressurised inhalation, suspension, inhalation 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 budesonide / glycopyrronium bromide / formoterol (fumarate), pressurised inhalation, suspension, inhalation 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 budesonide / glycopyrronium bromide / formoterol (fumarate), pressurised inhalation, suspension, inhalation 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 Pearl Therapeutics, Inc., 200 Cardinal Way, 94063 - Redwood City, United States.

EMA/PDCO/550085/2017
London, 10 November 2017

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

EMEA-002063-PIP01-16

Scope of the application

Active substance(s):

Budesonide / glycopyrronium bromide / formoterol (fumarate)

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Pressurised inhalation, suspension

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Pearl Therapeutics, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Pearl Therapeutics, Inc. submitted for agreement to the European Medicines Agency on 12 September 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 18 October 2016.

Supplementary information was provided by the applicant on 20 August 2017. 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 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 6 years;
- pressurised inhalation, suspension; inhalation 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:

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

For the regular treatment of asthma in children and adolescents 6 to less than 18 years of age where use of a triple combination medicinal product is appropriate

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)

Pressurised inhalation, suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	6	**Study 1:** Randomised, double-blind, parallel group, placebo controlled 6-month dose confirmation study to evaluate the efficacy and safety of 3 doses of glycopyrronium (GP) metered-dose inhaler (MDI) and open label Spiriva Respimat compared to placebo MDI in symptomatic adolescents (and adults) with asthma receiving low to high-dose inhaled corticosteroids (ICS)/long-acting beta agonists (LABA). (PT001102)

		Study 2: Randomised, double blind, double dummy, active controlled, parallel group, study to assess the effects of budesonide, glycopyrronium and formoterol fumarate inhalation suspension [BGF metered dose inhaler (MDI)] relative to budesonide and formoterol fumarate inhalation suspension (BFF) and Seretide on lung function, moderate to severe exacerbation, symptoms and Quality of Life (QoL) over a 24-52 week variable length period in adolescents (and adults) with asthma. (PT010102) **Study 3:** Randomised, double-blind, double dummy, active controlled, parallel group, 24-52- week, variable length study to assess the efficacy and safety of BGF MDI compared to BFF MDI and Seretide MDI, as an active control, on lung function, asthma exacerbations, symptoms and Quality of Life (QoL) in adolescent (and adult) subjects with asthma. (PT010103) **Study 4:** Randomised, double-blind, placebo-controlled, chronic dosing (3 weeks), 4-period crossover study comparing the efficacy and safety of 3 doses of Glycopyrronium Inhalation Suspension (GP MDI) with placebo MDI in children 6 to less than 12 years of age with asthma. **Study 5:** Randomised, double-blind, parallel group, 24-52 week variable length study with an open label arm to assess the efficacy and safety of BGF MDI compared to BFF MDI on lung function and on moderate/severe asthma exacerbations in subjects 6 to less than 12 years of age with asthma. **Study 6:** Open-label, single-period, single-dose study to assess the pharmacokinetics (PK) of BGF MDI in children 6 to less than 12 years of age with asthma.
Extrapolation, modelling and simulation studies	0	Not applicable
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