EMA/181827/2017

European Medicines Agency decision

P/0112/2017

of 11 April 2017

on the agreement of a paediatric investigation plan and on the granting of a waiver for olodaterol (hydrochloride) (Striverdi Respimat), (EMEA-001965-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 Boehringer Ingelheim International GmbH on 12 May 2016 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 February 2017, in accordance with Article 18 of Regulation (EC) No 1901/2006 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 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 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 olodaterol (hydrochloride) (Striverdi Respimat), inhalation solution, 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 waiver for olodaterol (hydrochloride) (Striverdi Respimat), inhalation solution, 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

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 - Ingelheim am Rhein, Germany.

EMA/PDCO/861653/2016
London, 24 February 2017

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

EMEA-001965-PIP01-16

Scope of the application

Active substance(s):

Olodaterol (hydrochloride)

Invented name:

Striverdi Respimat

Condition(s):

Treatment of cystic fibrosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Inhalation solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH 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 waiver under Article 13 of said Regulation.

The procedure started on 21 June 2016.

Supplementary information was provided by the applicant on 12 December 2016. 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 18 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   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 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

Treatment of cystic fibrosis

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- inhalation solution, inhalation use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition

Treatment of cystic fibrosis

2.1.1. Indication(s) targeted by the PIP

Maintenance bronchodilator treatment in conjunction with standard therapies to improve pulmonary function in patients with cystic fibrosis

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Inhalation solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	4	**Study 1** (1222.57) Placebo-controlled dose-ranging cross-over trial in adolescent (age 12 to less than 18 years) and (adult) CF patients. **Study 2** (1222.58) Randomised, double-blind, placebo-controlled parallel-group efficacy and safety study of at least 26-week in adolescent (and adult) CF patients.

		Study 3 (1222.59) Randomised, double-blind, placebo-controlled parallel-group efficacy and safety study of at least 26-weeks in children with CF, 6 to less than 12 years of age. **Study 4** (1222.60) Randomized, double-blind, placebo-controlled parallel-group safety study in children with CF less than 6 years of age.
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:	Yes
Date of completion of the paediatric investigation plan:	By November 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

Treatment of chronic obstructive pulmonary disease

Authorised indication(s):

- Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD).

Authorised pharmaceutical form(s)

Inhalation solution

Authorised route(s) of administration

Inhalation use