EMA/910691/2011

European Medicines Agency decision

P/285/2011

of 30 November 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for budesonide (Budiair and associated names) (EMEA-001120-PIP01-10) 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 Neurosis Consortium on 13 December 2010 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 14 October 2011, 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 budesonide (Budiair and associated names), Pressurised 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 budesonide (Budiair and associated names), Pressurised 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 4

This decision is addressed to Neurosis Consortium, University Children's Hospital - Calwerstrasse, 7, 72076 - Tuebingen, Germany.

Done at London, 30 November 2011

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/910691/2011

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

EMEA-001120-PIP01-10

Scope of the application

Active substance(s):

Budesonide

Invented name:

Budiair and associated names

Condition(s):

Prevention of bronchopulmonary dysplasia

Pharmaceutical form(s):

Pressurised inhalation, solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Neurosis Consortium

Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Neurosis Consortium submitted for agreement to the European Medicines Agency on 13 December 2010 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 19 January 2011.

Supplementary information was provided by the applicant on 1 August 2011. 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 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 Icelandic and the Norwegian Paediatric Committee members agree 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(es) and appendix.

London, 14 October 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition:

Prevention of Bronchopulmonary Dysplasia (BPD)

The waiver applies to:

- All subsets of the paediatric population from 28 weeks of gestational age to less than 18 years of age;
- for pressurised inhalation, solution, 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: Prevention of Bronchopulmonary Dysplasia (BPD).

2.1.1. Indication(s) targeted by the PIP

Prevention of Bronchopulmonary Dysplasia (BPD) in preterm newborn infants.

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

From 23 to less than 28 weeks of gestational age (GA).

2.1.3. Pharmaceutical form(s)

Pressurised inhalation, solution

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	4	**Study 1** Randomized, double-blind, placebo-controlled, multicentre trial to evaluate safety and efficacy of budenoside for the prevention of bronchopulmonary dysplasia (BPD) in preterm infants from 23 to less than 28 weeks of GA including a long-term follow-up at the corrected age of 18-22 months. **Study 2** Substudy to study 1 to evaluate pharmacokinetics (PK) / pharmacodynamics (PD).

Area	Number of studies	Description
		Study 3 Substudy to study 1 to evaluate genetic susceptibility to bronchopulmonary dysplasia. **Study 4** Substudy to study 1 to evaluate pituary / adrenal gland function.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2016
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of asthma

Authorised indications:

Treatment of mild, moderate, and severe persistent asthma in adolescents and adults.

Treatment of mild, moderate, and severe persistent asthma in children from 6 to 12 years of age.

Treatment of asthma requiring maintenance treatment with glucocorticosteroids for control of underlying airway inflammation in adults, adolescents and children from 2 to 12 years.

2. Treatment of chronic obstructive pulmonary disease (COPD)

Authorised indications:

Treatment of advanced chronic obstructive pulmonary disease (COPD) where a response to inhaled corticosteroids has been confirmed by clinical and/or spirometric evidence.

Treatment of bronchial asthma and other chronic obstructive airways diseases, for which a corticosteroid therapy is necessary.

Invented name	Strength	Pharmaceutical form	Route of administration
Acorspray	200 mcg/actuation	Pressurised inhalation, solution	Inhalation use
Budesonida Budiair	200 mcg/actuation	Pressurised inhalation, solution	Inhalation use
Budiair	200 mcg/actuation	Pressurised inhalation, solution	Inhalation use
Deso	200 mcg/actuation	Pressurised inhalation, solution	Inhalation use
Esprit	200 mcg/actuation	Pressurised inhalation, solution	Inhalation use
Miflo	200 mcg/actuation	Pressurised inhalation, solution	Inhalation use
Ribujet	200 mcg/actuation	Pressurised inhalation, solution	Inhalation use