EMA/615425/2010

European Medicines Agency decision

P/210/2010

of 29 October 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for prucalopride succinate (Resolor), (EMEA-000459-PIP01-08) 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 Movetis NV on 11 September 2009 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 September 2010, 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 prucalopride succinate (Resolor), film-coated tablet, oral solution, 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 prucalopride succinate (Resolor), film-coated tablet, oral solution, 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 prucalopride succinate (Resolor), film-coated tablet, oral solution, 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 Movetis NV, Veedijk 58 (1004), 2300 Turnhout, Belgium.

Done at London, 29 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/517911/2010

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

EMEA-000459-PIP01-08

Scope of the application

Active substance(s):

Prucalopride succinate

Invented name:

Resolor

Condition(s):

Treatment of chronic constipation

Treatment of opioid-induced constipation

Authorised indication(s): see Annex II

Pharmaceutical form(s):

Film-coated tablet

Oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Movetis NV

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, Movetis NV submitted for agreement to the European Medicines Agency on 11 September 2009 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 15 October 2009.

Supplementary information was provided by the applicant on 28 June 2010.

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 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, 10 September 2010

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:

Treatment of chronic constipation

The waiver applies to:

- The paediatric population from birth to less than 6 months;
- for film-coated tablets and oral solution, for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.2. Condition:

Treatment of opioid-induced constipation

The waiver applies to:

- The paediatric population from birth to less than 2 years of age;
- for film-coated tablets and oral solution, for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of chronic constipation

2.1.1. Indication(s) targeted by the PIP

Symptomatic treatment of functional constipation in children aged from 6 months to 18 years.

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Film-coated tablet, 2 mg
- Oral solution 0.4, mg/ml

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of liquid age appropriate formulation and strength for oral use.
Non-clinical	1	Study 2 Non-clinical study to investigate the toxicity and toxicokinetics of prucalopride in juvenile rats.
Clinical	1	Study 3 Double-blind placebo-controlled trial to evaluate efficacy, safety, tolerability and pharmacokinetics of prucalopride in children with functional constipation from 6 months to less than 18 years of age, with open-label comparator (PEG) controlled extension to evaluate safety and tolerability up to 24 weeks.

2.2. Condition:

Treatment of opioid-induced constipation.

2.2.1. Indication(s) targeted by the PIP

Symptomatic treatment of opioid-induced constipation resulting from chronic opioid use in children aged from 2 to 18 years.

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

From 2 years to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

- Film-coated tablet, 2 mg
- Oral solution 0.4, mg/ml

2.2.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Same study as for treatment of chronic constipation.
Non-clinical	1	Study 2 Same study as for treatment of chronic constipation.
Clinical	1	Study 4 Open-label trial to evaluate the efficacy, safety and tolerability of prucalopride in children from 2 years to less than18 years of age with opioid-induced constipation.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of chronic constipation

   Authorised indications: Symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EMEA/H/C/001012	Resolor	2 mg	Film-coated tablet	Oral use	Blister (alu/alu)	0.4 mg/ml	28 x 1 tablets