EMA/392509/2013

European Medicines Agency decision

P/0154/2013

of 5 July 2013

on the acceptance of a modification of an agreed paediatric investigation plan for selexipag (EMEA-000997-PIP01-10-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for selexipag (EMEA-000997-PIP01-10-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 European Medicines Agency's decision P/246/2011 issued on 21 October 2011,

Having regard to the application submitted by Actelion Registration Ltd on 21 February 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 May 2013, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for selexipag, film-coated tablet, tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Actelion Registration Ltd, 389 Chiswick High Road, W44 4AL UK London, United Kingdom.

Done at London, 5 July 2013

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

EMA/PDCO/141222/2013

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000997-PIP01-10-M01

Scope of the application

Active substance(s):

Selexipag

Condition(s):

Treatment of pulmonary arterial hypertension

Pharmaceutical form(s):

Film-coated tablet

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Actelion Registration Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Actelion Registration Ltd submitted to the European Medicines Agency on 21 February 2013 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/246/2011 issued on 21 October 2011.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 20 March 2013.

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Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   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 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.

London, 17 May 2013

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 pulmonary arterial hypertension

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- for film-coated tablet, oral use;
- and for Tablet, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

And to:

- the paediatric population from 1 to less than 7 years of age;
- for film-coated tablet, oral 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 pulmonary arterial hypertension

2.1.1. Indication(s) targeted by the PIP

Treatment of pulmonary arterial hypertension (PAH).

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)

Film-coated tablet.

Tablet (mini tablet).

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1: Development of mini tablets (diameter ≤ 3mm), which can be taken dispersed in water.
Non-clinical	2	Measure 2: 28 day dose range finding toxicity study in juvenile dogs. Measure 3: 39 week toxicity study in juvenile dogs.
Clinical	2	Measure 4: Double-blind, randomised, multicentre, placebo-controlled trial to evaluate efficacy, safety, tolerability and pharmacokinetics of selexipag in children from 7 to less than 18 years of age with pulmonary hypertension. Measure 5: Double-blind, randomised, multicentre, placebo-controlled trial to evaluate efficacy, safety, tolerability and pharmacokinetics of selexipag in children from 1 to less than 7 years of age with pulmonary hypertension.

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 March 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes