EMA/463403/2010

European Medicines Agency decision

P/124/2010

of 28 July 2010

on the acceptance of a modification of an agreed paediatric investigation plan for voclosporin (EMEA-000132-PIP01-07-M02) 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 voclosporin (EMEA-000132-PIP01-07-M02) 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/126/2008 issued on 23 December 2008, and the decision P/7/2010 issued on 26 January 2010,

Having regard to the application submitted by Lux Biosciences GmbH on 1 April 2010 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 11 June 2010, 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 and to the deferral.

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

[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 voclosporin, soft capsules and oral liquid, oral use, including changes to a deferral, 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 Lux Biosciences GmbH, Dreieichstr. 59, 60594 Frankfurt, Germany.

Done at London, 28 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/363406/2010

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

EMEA-000132-PIP01-07-M02

Scope of the application

Active substance(s):

Voclosporin

Condition(s):

Chronic non-infectious uveitis

Pharmaceutical form(s):

Soft capsules

Oral liquid

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Lux Biosciences GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Lux Biosciences GmbH submitted to the European Medicines Agency on 1 April 2010 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/126/2008 issued on 23 December 2008, and the decision P/7/2010 issued on 26 January 2010.

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

The procedure started on 15 April 2010.

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Scope of the modification

The change relates to a modification of the timeline for one of the measures.

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 deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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, 11 June 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Chronic non-infectious uveitis

2. Waiver

2.1. Condition

Chronic non-infectious uveitis

The waiver applies to:

- Newborn, infants and toddlers from birth to less than 24 months
- for soft capsules and oral liquid, oral use
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Chronic non-infectious uveitis

3.1.1. Indication targeted by the PIP

Treatment of chronic non-infectious uveitis

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

From 2 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Soft capsules (5 mg and 10 mg)

Oral liquid

3.1.4. Studies

Area	Number of studies	Description
Quality	1	Development of an oral liquid formulation
Non-clinical	1	Juvenile animal toxicity study
Clinical	3	Open-label, multi-centre, dose-titration study of voclosporin for the treatment of non-infectious uveitis in children from 6 years to less than 18 years of age. Open-label, multi-centre study to evaluate safety and efficacy of voclosporin for the treatment of non-infectious uveitis in children from 6 years to less than 18 years of age. Multi-centre study to assess the safety and efficacy of voclosporin in the treatment of non-infectious uveitis in children from 2 to less than 6 years of age.

4. 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 April 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes