EMA/532947/2018

European Medicines Agency decision

P/0273/2018

of 14 August 2018

on the acceptance of a modification of an agreed paediatric investigation plan for landiolol (hydrochloride) (Rapibloc, Landiobloc, Raploc, Runrapiq), (EMEA-001150-PIP02-13-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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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/0283/2014 issued on 30 October 2014 and the decision P/0187/2016 issued on 15 July 2016,

Having regard to the application submitted by AOP Orphan Pharmaceuticals AG on 9 April 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 July 2018, 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 landiolol (hydrochloride) (Rapibloc, Landiobloc, Raploc, Runrapiq), powder for solution for infusion, concentrate for solution for injection, intravenous use, including changes to the 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 AOP Orphan Pharmaceuticals AG, Wilhelminenstraße 91/II f, 1160 - Vienna, Austria.

EMA/PDCO/433495/2018 Rev
London, 27 July 2018

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

EMEA-001150-PIP02-13-M02

Scope of the application

Active substance(s):

Landiolol (hydrochloride)

Invented name:

Rapibloc, Landiobloc, Raploc, Runrapiq

Condition(s):

Treatment of supraventricular arrhythmias

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for infusion

Concentrate for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

AOP Orphan Pharmaceuticals AG

Information about the authorised medicinal product:

See Annex II

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Basis for revised opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AOP Orphan Pharmaceuticals AG submitted to the European Medicines Agency on 9 April 2018 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0283/2014 issued on 30 October 2014 and the decision P/0187/2016 issued on 15 July 2016.

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

The procedure started on 2 May 2018.

An Opinion was adopted by the Paediatric Committee on 29 June 2018, recommending refusal of the proposed modification. AOP Orphan Pharmaceuticals AG received the Paediatric Committee opinion on 9 July 2018.

On 9 July 2018 the applicant brought to the attention of the Paediatric Committee that part of their response to the Day 30 Report of the Paediatric Committee has not been assessed, which could have an impact on the acceptability of the proposed modification.

The Paediatric Committee considered that there is a need to revise its opinion on basis of the additional information identified. The revision procedure started on 10 July 2018.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Revised 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 the changes to the paediatric investigation plan and 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 agreed paediatric investigation plan are set out in the Annex I.

This revised 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of supraventricular arrhythmias

2.1.1. Indication(s) targeted by the PIP

Treatment of supraventricular tachyarrhythmias

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of powder for solution suitable for paediatric use.
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 2** Multicentre open-label uncontrolled study to investigate the effectiveness and safety of landiolol in controlling supraventricular tachycardia including inappropriate sinus tachycardia, junctional ectopic tachycardia, atrial flutter, atrial fibrillation, focal atrial tachycardia; and atrioventricular nodal re-entry tachycardia and atrioventricular reciprocating (re-entry) tachycardia refractory to treatment with adenosine in surgical (peri- and postoperative, cardiac and non-cardiac surgery) and non- surgical paediatric patients (AOP LDLL300.301).
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:	No
Date of completion of the paediatric investigation plan:	By December 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of supraventricular arrhythmias

Authorised indication(s):

- Supraventricular tachycardia and for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other circumstances where short-term control of the ventricular rate with a short acting agent is desirable.
- Non-compensatory sinus tachycardia where, in the physician's judgment the rapid heart rate requires specific intervention.

Authorised pharmaceutical form(s):

Powder for solution for infusion

Concentrate for solution for injection

Authorised route(s) of administration:

Intravenous use