EMA/236236/2023

European Medicines Agency decision

P/0221/2023

of 14 June 2023

on the acceptance of a modification of an agreed paediatric investigation plan for landiolol (hydrochloride) (Rapibloc, Landiobloc, Raploc, Runrapiq), (EMEA-001150-PIP02-13-M05) 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 Union procedures for the authorisation and supervision of medicinal products for human 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, the decision P/0187/2016 issued on 15 July 2016, the decision P/0273/2018 issued on 14 August 2018, and the decision P/0161/2021 issued on 16 April 2021,

Having regard to the application submitted by AOP Orphan Pharmaceuticals GmbH on 17 January 2023 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 26 April 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

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, intravenous bolus 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 AOP Orphan Pharmaceuticals GmbH, Leopold-Ungar-Platz 2, 1190 – Vienna, Austria.

EMA/PDCO/41465/2023
Amsterdam, 26 April 2023

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

EMEA-001150-PIP02-13-M05

Scope of the application

Active substance(s):

Landiolol (hydrochloride)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of supraventricular arrhythmias

Pharmaceutical form(s):

Powder for solution for infusion

Concentrate for solution for injection

Route(s) of administration:

Intravenous use

Intravenous bolus use

Name/corporate name of the PIP applicant:

AOP Orphan Pharmaceuticals GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AOP Orphan Pharmaceuticals GmbH submitted to the European Medicines Agency on 17 January 2023 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, the decision P/0187/2016 issued on 15 July 2016, the decision P/0273/2018 issued on 14 August 2018, and the decision P/0161/2021 issued on 16 April 2021.

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

The procedure started on 27 February 2023.

Scope of the modification

Some measures 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 Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan 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 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	Description
Quality-related studies	**Study 1** Study 1 deleted in procedure EMEA-001150-PIP02-13-M05
Non-clinical studies	Not applicable.
Clinical studies	**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	Not applicable.
Other studies	**Study 3** Single centre, retrospective medical chart review study to investigate the efficacy and safety of landiolol in controlling tachycardia in patients treated in a department of neonatology and paediatric intensive care.
Other measures	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 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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.
  - Invented name(s): Rapibloc, Landiobloc, Raploc, Runrapiq
  - Authorised pharmaceutical form(s): Powder for solution for infusion;

    Concentrate for solution for injection
  - Authorised route(s) of administration: Intravenous use
  - Authorised via decentralised procedure
- Non-compensatory sinus tachycardia where, in the physician's judgment the rapid heart rate requires specific intervention.
  - Invented name(s): Rapibloc, Landiobloc, Raploc, Runrapiq
  - Authorised pharmaceutical form(s): Powder for solution for infusion;

    Concentrate for solution for injection
  - Authorised route(s) of administration: Intravenous use
  - Authorised via decentralised procedure