MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-101335-PIP01-24-M01

Scope of the Application

Active Substance(s)

LANDIOLOL HYDROCHLORIDE

Condition(s)

Treatment of supraventricular arrhythmias.

Pharmaceutical Form(s)

Powder for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

AOP ORPHAN PHARMACEUTICALS GMBH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AOP ORPHAN PHARMACEUTICALS GMBH submitted to the licensing authority on 23/01/2024 14:45 GMT an application for a Modification

The procedure started on 09/08/2024 11:22 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101335-PIP01-24-M01

Of 28/08/2024 13:40 BST

On the adopted decision for LANDIOLOL HYDROCHLORIDE (MHRA-101335-PIP01-24-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for LANDIOLOL HYDROCHLORIDE, Powder for solution for infusion Concentrate for solution for injection , INTRAVENOUS USE .

This decision is addressed to AOP ORPHAN PHARMACEUTICALS GMBH, Leopold-Ungar-Platz 2, Vienna, AUSTRIA, 1190

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of supraventricular arrhythmias

2.2 Indication(s) targeted by the PIP:

Treatment of supraventricular arrhythmias

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Powder for solution for infusion Concentrate for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 This study was deleted during the procedure MHRA-101335-PIP01-24-M01.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (LDLL300.301) Multicentre open-label uncontrolled study to investigate the effectiveness and safety of landiolol in controlling supraventricular tachycardia including inappropriate sinus tachycardia, junctional ectopic tachycardia (JET), atrial flutter (AFL), atrial fibrillation (AF), focal atrial tachycardia (FAT); and atrioventricular nodal re-entry tachycardia (AVNRT) and atrioventricular reciprocating (re-entry) tachycardia (AVRT) refractory to treatment with adenosine in surgical (peri- and post-operative, cardiac and non-cardiac surgery) and non-surgical paediatric patients.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	1	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	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/05/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes