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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100349-PIP01-21-M01

Scope of the Application

Active Substance(s)

Rezafungin acetate

Condition(s)

Treatment of invasive candidiasis

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion; Age appropriate dosage form for parenteral use.

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Napp Pharmaceuticals Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Napp Pharmaceuticals Limited submitted to the licensing authority on 12/11/2021 15:50 GMT an application for a Modification

The procedure started on 26/04/2022 15:52 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-100349-PIP01-21-M01

Of 04/05/2022 17:06 BST

On the adopted decision for Rezafungin acetate (MHRA-100349-PIP01-21-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 Rezafungin acetate, Powder for concentrate for solution for infusion; Age appropriate dosage form for parenteral use. , Intravenous use .

This decision is addressed to Napp Pharmaceuticals Limited, Unit 196, Cambridge Science Park, Milton Road, Cambridge, United Kingdom, CB4 0AB

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of invasive candidiasis

2.2 Indication(s) targeted by the PIP:

Treatment of invasive candidiasis

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for concentrate for solution for infusion; Age appropriate dosage from for parenteral use

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate dosage form for parenteral use suitable for the paediatric population from birth with polysorbate 80 level safe for young infants.
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 Open-label, uncontrolled trial to evaluate PK, safety and tolerability of single IV dose of rezafungin acetate profile in children from birth to less than 18 years of age with suspected or confirmed fungal infection. Study 3 Open label randomised, active controlled trial to evaluate the safety, tolerability and efficacy of rezafungin acetate in children from birth to less than 18 years of age with suspected or confirmed invasive candidiasis.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
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:	30/11/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes