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-101117-PIP01-23-M01

Scope of the Application

Active Substance(s)

ORITAVANCIN

Condition(s)

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

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

Menarini International Operations Luxembourg S.A

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Menarini International Operations Luxembourg S.A submitted to the licensing authority on 26/09/2023 13:04 BST an application for a Modification

The procedure started on 27/09/2023 16:05 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-101117-PIP01-23-M01

Of 13/10/2023 12:46 BST

On the adopted decision for ORITAVANCIN (MHRA-101117-PIP01-23-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 ORITAVANCIN, Powder for concentrate for solution for infusion; Age appropriate dosage form for parenteral use. , INTRAVENOUS USE .

This decision is addressed to Menarini International Operations Luxembourg S.A, 1, Avenue de la Gare, Luxembourg, LUXEMBOURG, L-1611

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

2.2 Indication(s) targeted by the PIP:

Treatment of acute bacterial skin and skin structure infections

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):

Age-appropriate dosage form for parenteral use Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Age-appropriate dosage form for parenteral use for the paediatric population from birth to less than 3 months of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 (TMC-ORI-11-01) Open-label, dose-finding trial to evaluate PK, safety and tolerability of oritavancin single dose infusion in children from birth to less than 18 years of age with confirmed or suspected bacterial infections receiving antibiotic therapy. Study 3 Open label trial to evaluate PK, safety and tolerability of oritavancin in children from birth to less than 3 months of age with confirmed or suspected bacterial infections receiving antibiotic therapy.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Pop PK and pop PK/PD modelling and simulation study in paediatric patients from birth to less than 18 years of age to inform dosing recommendation of oritavancin in paediatric subjects from birth to less than 18 years.
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:	Yes
Date of completion of the paediatric investigation plan:	31/07/2024

Deferral of one or more studies contained in the paediatric investigation plan:	Yes