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-100262-PIP01-21-M01

Scope of the Application

Active Substance(s)

DALBAVANCIN HYDROCHLORIDE

Condition(s)

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

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Allergan Pharmaceuticals International Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Allergan Pharmaceuticals International Limited submitted to the licensing authority on 29/10/2021 12:05 BST an application for a Modification

The procedure started on 07/03/2022 12:56 GMT

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-100262-PIP01-21-M01

Of 31/03/2022 13:20 BST

On the adopted decision for DALBAVANCIN HYDROCHLORIDE (MHRA-100262-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 DALBAVANCIN HYDROCHLORIDE, Powder for concentrate for solution for infusion , Intravenous use .

This decision is addressed to Allergan Pharmaceuticals International Limited, Clonshaugh Business & Technology Park, Dublin, Ireland, D17 E400

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 (ABSSSI) caused by susceptible Gram positive bacteria.

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 concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 Study deleted with EMEA-000016-PIP01-07-M06
Non-Clinical Studies	2	Study 2 Dose range finding study with dalbavancin in neonatal rat Study 3 Definitive juvenile rat toxicology study of dalbavancin
Clinical Studies	4	Study 4 Paediatric pharmacokinetic study for the determination of pharmacokinetics of dalbavancin in paediatric patients aged 12 to less than 18 years for selection of dosing for a Phase 3 study for children with acute bacterial skin and skin structure infections Study 5 Paediatric pharmacokinetic study for the determination of pharmacokinetics of dalbavancin in paediatric patients aged 3 months to less than 12 years for selection of dosing for a Phase 3 study in children with acute bacterial skin and skin structure infections Study 6 Paediatric pharmacokinetic study for the determination of pharmacokinetics of dalbavancin in paediatric patients aged less than 3 months with suspected or confirmed bacterial infections for selection of dosing for a phase 3 study in children with late-onset sepsis Study 7 Paediatric safety and efficacy study for the determination of safety and efficacy of dalbavancin in acute bacterial skin and skin structure infections in patients aged from birth to less than 18 years of age requiring hospitalization and intravenous antibiotic therapy Study 8 Study

		deleted in EMEA-000016-PIP01-07-M06
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:	Yes
Date of completion of the paediatric investigation plan:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes