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 (MHRA-100262-PIP01-21-M01)

MHRA-100262-PIP01-21-M02

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

AbbVie Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd submitted to the licensing authority on 18/01/2024 10:26 GMT an application for a Modification

The procedure started on 12/02/2024 13:18 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

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-M02

Of 03/06/2024 10:39 BST

On the adopted decision for DALBAVANCIN HYDROCHLORIDE (MHRA-100262-PIP01-21-M02) 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 AbbVie Ltd, AbbVie House, Vanwall Road, Maidenhead, UNITED KINGDOM, SL64UB

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