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 (MHRA-101212-PIP01-23-M01) and to the deferral

MHRA-101212-PIP01-23-M02

Scope of the Application

Active Substance(s)

ENMETAZOBACTAM; CEFEPIME DIHYDROCHLORIDE MONOHYDRATE

Condition(s)

Treatment of infections caused by gram-negative organisms

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Allecra Therapeutics GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Allecra Therapeutics GmbH submitted to the licensing authority on 29/07/2025 15:12 BST an application for a Modification

The procedure started on 02/09/2025 19:11 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-101212-PIP01-23-M02

Of 05/12/2025 08:34 GMT

On the adopted decision for ENMETAZOBACTAM; CEFEPIME DIHYDROCHLORIDE MONOHYDRATE (MHRA-101212-PIP01-23-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 ENMETAZOBACTAM; CEFEPIME DIHYDROCHLORIDE MONOHYDRATE, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Allecra Therapeutics GmbH , Dashwood House, 69 Old Broad Street, , London, UNITED KINGDOM, 79539

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of infections caused by gram-negative organisms

2.2 Indication(s) targeted by the PIP:

2.1.1. Indication(s) targeted by the PIP Treatment of complicated urinary tract infections (cUTI), including pyelonephritis Treatment of hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the above 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):

Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate dosage formulation(s) for parenteral use of fixed dose combination (FDC) of cefepime and enmetazobactam at a ratio to be determined based on Study 5 in paediatric subjects from birth to less than 18 years of age.
Non-Clinical Studies	2	Study 2 Definitive juvenile toxicity study in rats at a developmental age of 10 days via subcutaneous administration. Study 3 Definitive juvenile toxicity study in rats at a developmental age of 21 days via intravenous administration.
Clinical Studies	1	Study 4 Open-label, multi-dose study to assess the pharmacokinetics, safety and tolerability of cefepime/ enmetazobactam in paediatric subjects from birth to less than 18 years of age with suspected or confirmed complicated urinary infections (cUTI).
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation study to evaluate the use of cefepime and enmetazobactam for the treatment of paediatric subjects from birth to less than 18 years of age with certain infections caused by Gram negative bacteria. Study 6 Extrapolation study to evaluate the use of cefepime and enmetazobactam

		for the treatment of paediatric subjects from birth to less than 18 years of age with certain infections caused by Gram negative bacteria.
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:	31/03/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes