EMA/672733/2022

European Medicines Agency decision

P/0340/2022

of 10 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for enmetazobactam / cefepime (EMEA-002240-PIP02-17-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

European Medicines Agency decision

P/0340/2022

of 10 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for enmetazobactam / cefepime (EMEA-002240-PIP02-17-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0093/2019 issued on 22 March 2019,

Having regard to the application submitted by Allecra Therapeutics GmbH on 15 March 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 June 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for enmetazobactam / cefepime, powder for solution for infusion, intravenous use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Allecra Therapeutics GmbH, c/o Loeba Treuhand GmbH, Wallbrunnstrasse 24, 79539 – Lörrach, Germany.

EMA/PDCO/194699/2022 corr
Amsterdam, 24 June 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002240-PIP02-17-M01

Scope of the application

Enmetazobactam / Cefepime

Condition(s):

Treatment of urinary tract infections

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Allecra Therapeutics GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allecra Therapeutics GmbH submitted to the European Medicines Agency on 15 March 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0093/2019 issued on 22 March 2019.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 25 April 2022.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

    - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of urinary tract infections (UTI)

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated urinary tract infections

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for infusion

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of age-appropriate dosage formulation(s) for parenteral use of fixed dose combination (FDC) of cefepime and AA101 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	**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	**Study 4** Open-label, multi-dose, PK, safety and tolerability study in paediatric subjects from birth to less than 18 years of age with suspected or confirmed complicated urinary infections (cUTI) suspected to be susceptible to cefepime.

Extrapolation, modelling and simulation studies	**Study 5** Modelling and simulation study to evaluate the use of cefepime and AAI101 for the treatment of paediatric subjects from birth to less than 18 years of age with suspected or confirmed complicated urinary tract infections. **Study 6** Extrapolation study to evaluate cefepime/AAI101 for the treatment of paediatric subjects from birth to less than 18 years of age with suspected or confirmed complicated UTI.
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes