EMA/107378/2019

European Medicines Agency decision

P/0093/2019

of 22 March 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for 1-{[(2S,3S)-2-carboxylato-3-methyl-4,4,7-trioxo-4-{6}-thia-1-azabi-cyclo[3.2.0]heptan-3-yl]methyl}-3-methyl-1H-1,2,3-triazol-3-ium (AAI101) (EMEA-002240-PIP02-17) 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.

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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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Allecra Therapeutics GmbH on 8 December 2017 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 February 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for 1-{[(2S,3S)-2-carboxylato-3-methyl-4,4,7-trioxo-4-{6}-thia-1-azabi-cyclo[3.2.0]heptan-3-yl]methyl}-3-methyl-1H-1,2,3-triazol-3-ium (AAI101), powder for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for 1-{[(2S,3S)-2-carboxylato-3-methyl-4,4,7-trioxo-4-{6}-thia-1-azabi-cyclo[3.2.0]heptan-3-yl]methyl}-3-methyl-1H-1,2,3-triazol-3-ium (AAI101), powder for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Allecra Therapeutics GmbH, Im Kränzliacker 9, 79576 - Weil am Rhein, Germany.

EMA/PDCO/639129/2018
London, 1 February 2019

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-002240-PIP02-17

Scope of the application

Active substance(s):

1-{[(2S,3S)-2-carboxylato-3-methyl-4,4,7-trioxo-4-{6}-thia-1-azabi-cyclo[3.2.0]heptan-3-yl]methyl}-3-methyl-1H-1,2,3-triazol-3-ium (AAI101)

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 16(1) of Regulation (EC) No 1901/2006 as amended, Allecra Therapeutics GmbH submitted for agreement to the European Medicines Agency on 8 December 2017 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 3 April 2018.

Supplementary information was provided by the applicant on 16 October 2018. The applicant proposed modification to the paediatric investigation plan and withdrew its proposed waiver.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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	Number of measures	Description
Quality-related studies	1	**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	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, 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	2	**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	0	Not applicable
Other measures	0	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 March 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes