EMA/468349/2023

European Medicines Agency decision

P/0397/2023

of 27 October 2023

on the acceptance of a modification of an agreed paediatric investigation plan for eravacycline (Xerava), (EMEA-001555-PIP01-13-M05) 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 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/0046/2015 issued on 6 March 2015, the decision P/0336/2016 issued on 2 December 2016, the decision P/0251/2019 issued on 16 July 2019 and the decision P/0255/2020 issued on 15 July 2020,

Having regard to the application submitted by PAION Deutschland GmbH on 30 May 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 September 2023, 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.

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

[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 eravacycline (Xerava), powder for concentrate for solution for infusion, intravenous use, 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 PAION Deutschland GmbH, Heussstr. 25, 52078 – Aachen, Germany.

EMA/PDCO/269917/2023 Corr[1]
Amsterdam, 8 September 2023

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

EMEA-001555-PIP01-13-M05

Scope of the application

Active substance(s):

Eravacycline

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of complicated intra-abdominal infection

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

PAION Deutschland GmbH

[1] 16 October 2023

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, PAION Deutschland GmbH submitted to the European Medicines Agency on 30 May 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0046/2015 issued on 6 March 2015, the decision P/0336/2016 issued on 2 December 2016, the decision P/0251/2019 issued on 16 July 2019 and the decision P/0255/2020 issued on 15 July 2020.

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

The procedure started on 10 July 2023.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion.

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

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 annexes 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

1.1. Condition:

Treatment of complicated intra-abdominal infection.

The waiver applies to:

- the paediatric population from birth to less than 8 years of age;
- powder for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of complicated intra-abdominal infection.

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated intra-abdominal infection.

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

From 8 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** *Study 1 was deleted as a result of procedure EMEA-001555-PIP01-13-M02.*
Non-clinical studies	**Study 2** Definitive juvenile toxicity study to determine the toxicity of eravacycline following multiple dose administrations by intravenous injection to juvenile rats. **Study 3** Reprotox: (enhanced) pre- and post-natal development study to evaluate toxicity of eravacycline in F1 generation rats following intravenous administration of eravacycline to F0 dams during pregnancy and lactation.

Clinical studies	**Study 4 (TP-434-028)** Open-label single dose trial to evaluate pharmacokinetics and safety of intravenous (IV) eravacycline in children from 8 to less than 18 years of age with suspected or confirmed bacterial infection and receiving other systemic antibiotic therapy. **Study 5** *Study 5 was deleted as a result of procedure EMEA-001555-PIP01-13-M05.*
Modelling and simulation studies	**Study 6** Modelling and simulation study to evaluate the use of eravacycline for the treatment of complicated intra-abdominal infections in children from 8 years to less than 18 years of age. **Study 7** *Study 7 was deleted as a result of procedure EMEA-001555-PIP01-13-M05.*
Other studies	Not applicable.
Extrapolation plan	Studies 4 and 6 are part of an extrapolation plan covering the paediatric population from 8 years to less than 18 years of age, as agreed by the PDCO.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of complicated intra-abdominal infection

Authorised indication(s):

- Treatment of complicated intra-abdominal infections (cIAI) in adults
  - Invented name(s): Xerava
  - Authorised pharmaceutical form(s): Powder for concentrate for solution for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure