EMA/28203/2024

European Medicines Agency decision

P/0074/2024

of 8 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for oritavancin (diphosphate) (Tenkasi), (EMEA-001270-PIP01-12-M07) 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/0056/2013 issued on 25 March 2013, the decision P/0096/2017 issued on 11 April 2017, the decision P/0131/2019 issued on 17 April 2019, the decision P/0154/2021 issued on 16 April 2021, the decision P/0498/2021 issued on 3 December 2021, the decision P/0236/2022 issued on 8 July 2022, and the decision P/0104/2023 issued on 13 April 2023,

Having regard to the application submitted by Menarini International Operations Luxembourg S.A. on 9 October 2023 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 19 January 2024, 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 oritavancin (diphosphate) (Tenkasi), powder for concentrate for solution for infusion, age-appropriate dosage form for parenteral use, 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 Menarini International Operations Luxembourg S.A, 1, Avenue de la Gare, L-1611 – Luxembourg.

EMA/PDCO/480773/2023
Amsterdam, 19 January 2024

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

EMEA-001270-PIP01-12-M07

Scope of the application

Active substance(s):

Oritavancin (diphosphate)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acute bacterial skin and skin structure infections

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Age-appropriate dosage form for parenteral use

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Menarini International Operations Luxembourg S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Menarini International Operations Luxembourg S.A. submitted to the European Medicines Agency on 9 October 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0056/2013 issued on 25 March 2013, the decision P/0096/2017 issued on 11 April 2017, the decision P/0131/2019 issued on 17 April 2019, the decision P/0154/2021 issued on 16 April 2021, the decision P/0498/2021 issued on 3 December 2021, the decision P/0236/2022 issued on 8 July 2022, and the decision P/0104/2023 issued on 13 April 2023.

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

The procedure started on 20 November 2023.

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.

   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 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of acute bacterial skin and skin structure infections

2.1.1. Indication(s) targeted by the PIP

Treatment of acute bacterial skin and skin structure 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 concentrate for solution for infusion

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Description
Quality- related studies	**Study 1** Age-appropriate dosage form for parenteral use for the paediatric population from birth to less than 3 months of age
Non-clinical studies	Not applicable
Clinical studies	**Study 2** Open-label, dose-finding trial to evaluate PK, safety and tolerability of oritavancin single dose infusion in children from birth to less than 18 years of age with confirmed or suspected bacterial infections receiving antibiotic therapy (TMC-ORI-11-01) **Study 3** Open label trial to evaluate PK, safety and tolerability of oritavancin in children from birth to less than 3 months of age with confirmed or suspected bacterial infections receiving antibiotic therapy
Extrapolation, modelling and simulation studies	**Study 4** Pop PK and pop PK/PD modelling and simulation study in paediatric patients from birth to less than 18 years of age to inform dosing recommendation of oritavancin in paediatric subjects from birth to less than 18 years

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 July 2025
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 skin and subcutaneous tissue bacterial infections

Authorised indication(s):

- Tenkasi is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients aged 3 months and older (see sections 4.2, 4.4 and 5.1).
  - Invented name(s): Tenkasi
  - Authorised pharmaceutical form(s): Powder for concentrate for solution for infusion
  - Authorised route(s) of administration: Intravenous infusion
  - Authorised via centralised procedure