EMA/616492/2021

European Medicines Agency decision

P/0498/2021

of 3 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for oritavancin (diphosphate) (Tenkasi), (EMEA-001270-PIP01-12-M04) 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 European Medicines Agency's decision P/0056/2013 issued on 25 March 2013, the decision P/0096/2017 issued on 11 April 2017 and the decision P/0131/2019 issued on 17 April 2019 and the decision P/0154/2021 issued on 16 April 2021,

Having regard to the application submitted by Menarini International Operations Luxembourg S.A. on 12 July 2021 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 15 October 2021, 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.
[2] OJ L 136, 30.4.2004, p. 1.

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, Luxembourg.

EMA/PDCO/403255/2021
Amsterdam, 15 October 2021

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

EMEA-001270-PIP01-12-M04

Scope of the application

Active substance(s):

Oritavancin (diphosphate)

Invented name:

Tenkasi

Condition(s):

Treatment of acute bacterial skin and skin structure infections

Authorised indication(s):

See Annex II

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.

Information about the authorised medicinal product:

See Annex II

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 12 July 2021 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 and the decision P/0131/2019 issued on 17 April 2019 and the decision P/0154/2021 issued on 16 April 2021.

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

The procedure started on 17 July 2021.

Scope of the modification

Some measures and 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 Norwegian Paediatric Committee member 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	Number of measures	Description
Quality-related studies	1	**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	0	Not applicable.
Clinical studies	2	**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	1	**Study 4** Pop PK and pop PK/PD modelling and simulation study in paediatric

studies		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 December 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of acute bacterial skin and skin structure infections

Authorised indication(s):

- Tenkasi is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use