EMA/190111/2019

European Medicines Agency decision

P/0131/2019

of 17 April 2019

on the acceptance of a modification of an agreed paediatric investigation plan for oritavancin (diphosphate) (Orbactiv), (EMEA-001270-PIP01-12-M02) 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 and the decision P/0096/2017 issued on 11 April 2017,

Having regard to the application submitted by Rempex London Ltd on 19 November 2018 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 1 March 2019, 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) (Orbactiv), 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/836815/2018
London, 1 March 2019

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

EMEA-001270-PIP01-12-M02

Scope of the application

Active substance(s):

Oritavancin (diphosphate)

Invented name:

Orbactiv

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Rempex London Ltd submitted to the European Medicines Agency on 19 November 2018 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 and the decision P/0096/2017 issued on 11 April 2017.

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

The procedure started on 3 January 2019.

On 11 February 2019 Rempex London Ltd requested to transfer the paediatric investigation plan to Menarini International Operations Luxembourg S.A.

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 complicated acute bacterial skin and skin structure infections, caused by susceptible isolates of gram-positive microorganisms

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 12 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 diagnosed or suspected bacterial infections receiving antibiotic therapy. **Study 3** Evaluator-blind, randomised, multicentre, single dose, active controlled trial to evaluate safety and tolerability of oritavancin in children from birth to less than 18 years of age with acute bacterial skin and skin structure infections, suspected to be caused by gram-positive pathogens.

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 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):

- Orbactiv 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