

EMA/155550/2017

European Medicines Agency decision

P/0096/2017

of 11 April 2017

on the acceptance of a modification of an agreed paediatric investigation plan for oritavancin (diphosphate) (Orbactiv), (EMEA-001270-PIP01-12-M01) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0056/2013 issued on 25 March 2013,

Having regard to the application submitted by The Medicines Company on 6 December 2016 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 24 February 2017, 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 The Medicines Company, 8 Sylvan Way, NJ 07054 – Parsippany, United States.

EMA/PDCO/819626/2016
London, 24 February 2017

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

EMA-001270-PIP01-12-M01

Scope of the application

Active substance(s):

Oritavancin (diphosphate)

Invented name:

Orbactiv

Condition(s):

Treatment of skin and subcutaneous tissue bacterial 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:

The Medicines Company

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, The Medicines Company submitted to the European Medicines Agency on 6 December 2016 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 application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 3 January 2017.

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 skin and subcutaneous tissue bacterial infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated skin and subcutaneous tissue 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 skin and subcutaneous tissue bacterial 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 September 2022
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 skin and subcutaneous tissue bacterial 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