EMA/741979/2016

European Medicines Agency decision

P/0318/2016

of 2 December 2016

on the acceptance of a modification of an agreed paediatric investigation plan for telavancin (hydrochloride) (Vibativ), (EMEA-000239-PIP01-08-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/127/2009 issued on 14 July 2009 and the decision P/0111/2015 issued on 5 June 2015.

Having regard to the application submitted by Clinigen Healthcare Ltd on 11 July 2016 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 14 October 2016, 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 telavancin (hydrochloride) (Vibativ), powder for concentrate for solution for infusion, 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 Clinigen Healthcare Ltd Pitcairn House, Crown Square, First Avenue DE14 2WW - Burton-on-Trent, Staffordshire, United Kingdom.

EMA/PDCO/527180/2016
London, 14 October 2016

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

EMEA-000239-PIP01-08-M02

Scope of the application

Active substance(s):

Telavancin (hydrochloride)

Invented name:

Vibativ

Condition(s):

Treatment of complicated skin and soft tissue infections (cSSTI)

Treatment of nosocomial pneumonia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Clinigen Healthcare Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Clinigen Healthcare Ltd submitted to the European Medicines Agency on 11 July 2016 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/127/2009 issued on 14 July 2009 and the decision P/0111/2015 issued on 5 June 2015.

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

The procedure started on 16 August 2016.

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 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 skin and soft tissue infection (cSSTI)

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 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 nosocomial pneumonia (NP)

2.1.1. Indication(s) targeted by the PIP

Treatment of nosocomial pneumonia (NP)

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 250 mg and 750 mg vials

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	2	**Study 1** 7-day repeat dose toxicokinetic study in 4 day old rats following intravenous administration **Study 2** 6-weeks repeated dose study in neonate rats
Clinical studies	5	**Study 3** Open-label study of the safety and PK of single dose telavancin in paediatric patients from 1 to less than 18 years old

		Study 4 Open-label study of the safety and PK of single dose telavancin in paediatric patients less than 1 year of age **Study 5** Open-label study of the PK and safety of repeated dose telavancin in paediatric patients from 1 to less than 17 years old suspected of complicated infections with resistant Gram positive pathogens **Study 6** Randomized, open-label study of the safety and efficacy of telavancin in children from 1 to less than 17 years old suspected of nosocomial pneumonia with resistant Gram positive pathogens **Study 7** Randomized, open-label study of the safety and efficacy of telavancin in neonates and infants of less than 1 year of age suspected of nosocomial pneumonia by resistant Gram positive pathogens
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 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 nosocomial pneumonia

Authorised indication(s):

- VIBATIV is indicated for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

  VIBATIV should be used only in situations where it is known or suspected that other alternatives are not suitable (see sections 4.3, 4.4, 4.8 and 5.1).

  Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use