European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 14 July 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for Telavancin hydrochloride (EMEA-000239-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Astellas Pharma Europe B.V. on 25 June 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 May 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for Telavancin hydrochloride, lyophilisate for solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for Telavancin hydrochloride, lyophilisate for solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Astellas Pharma Europe B.V., Elisabethhof 19, 2353 EW, Leiderdorp, Netherlands.

Done at London, 14 July 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/320490/2009
EMEA-000239-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL

Scope of the application

Active substance(s):
Telavancin hydrochloride

Condition(s):
Complicated skin and soft tissue infections
Nosocomial pneumonia

Pharmaceutical form(s):
Lyophilisate for solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Astellas Pharma Europe B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe B.V. submitted for agreement to the EMEA on 25 June 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 31 July 2008.

Supplementary information was provided by the applicant on 6 March 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

- to grant a deferral in accordance with Article 21 of said Regulation

The Icelandic and the Norwegian Paediatric Committee members do agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 29 May 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

A. CONDITION(S)

Complicated skin and soft tissue infections
Nosocomial pneumonia

B. WAIVER

Not applicable.

C. PAEDIATRIC INVESTIGATION PLAN

- **Conditions to be investigated**

Complicated skin and soft tissue infections
Nosocomial pneumonia

- **Proposed PIP indication**

- Treatment of complicated skin and soft tissue infections
- Treatment of nosocomial pneumonia

- **Subset(s) of the paediatric population concerned by the paediatric development**

From birth to less than 18 years.

- **Formulation(s)**

Lyophilisate for solution for infusion 250 mg and 750 mg vials for intravenous use.

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	2	1. 7-day repeat dose toxicokinetic study in 4 day old rats following intravenous administration 2. 6-weeks repeated dose study in neonate rats
Clinical	5	1. Open-label study of the safety and PK of single dose telavancin in paediatric patients from 1 to less than 18 years old 2. Open-label study of the safety and PK of single dose telavancin in paediatric patients less than 1 year of age 3. 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 4. Randomized, open-label study of the safety and efficacy of telavancin in children from 1 to less than 17 years old suspected of complicated skin and soft tissue infection or nosocomial pneumonia with resistant Gram positive pathogens. 5. Randomized, open-label study of the safety and efficacy of telavancin in neonates and infants of less than 1 year of age suspected of complicated skin and soft tissue infection or nosocomial pneumonia by resistant Gram positive pathogens.

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By June 2020**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**