European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 19 June 2008

on the application for agreement of a Paediatric Investigation Plan for dalbavancin, EMEA-000016-PIP01-07 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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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 Pfizer Limited on 28 June 2007[t1] 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 04 June 2008[t2], 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, following a re-examination procedure of the Paediatric Committee's opinion of 11 April 2008 according to Article 25(3) of Regulation (EC) No 1901/2006 as amended, has given a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the 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 dalbavancin, powder 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 dalbavancin, powder for solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, CT13 9NJ.

Done at London, 19 June 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

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

EMEA/PDCO/281012/2008
EMEA-000016-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR (AFTER RE-EXAMINATION)

Scope of the application

Active substance:
Dalbavancin

Condition(s):
Skin and soft tissue infections

Pharmaceutical form(s):
Powder for solution for infusion.

Route(s) of administration:
Intravenous use.

Name/corporate name of the PIP applicant:
Pfizer Limited

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted for agreement to the EMEA on 28 June 2007 a paediatric investigation plan for the above mentioned medicinal product.

An Opinion was adopted by the Paediatric Committee on 11 April 2008 for the above mentioned product. Pfizer Limited received the Paediatric Committee Opinion on 16 April 2008.

On 7 May 2008 Pfizer Limited submitted to the EMEA a written request, including detailed grounds for re-examination of the Opinion.

The re-examination procedure started on 8 May 2008.

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Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for the re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, revises its opinion and recommends, as set out in the appended summary report :

- to agree the paediatric investigation plan in accordance with article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended

The Icelandic and the Norwegian Paediatric Committee members 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(ces).

London, 04 June 2008

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) / DISEASE(S)

Skin and soft tissue infections

B. Waiver

Not applicable

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Skin and soft tissue infections

- **PIP indication**

Complicated skin and soft tissue infections caused by susceptible Gram positive bacteria

- **Subset(s) covered**

All age subsets of the paediatric population

- **Formulation(s)**

Powder for solution for infusion

- **Studies / Measures**

Area	Subarea	Number	Description
Formulation			Development of a vial with smaller content and/or a lower strength appropriate for a paediatric population
Non-clinical	Toxicity	**2**	Dose Range Finding Study with Dalbavancin in Neonatal Rat Definitive Juvenile Rat Toxicology Study of Dalbavancin
Clinical	Pharmacokinetic	4	Paediatric Pharmacokinetic study: Determination of pharmacokinetics of dalbavancin in paediatric patients aged 12 through 17 years for selection of dosing in a Phase 3 therapeutic study for complicated skin and soft tissue infections.
	Pharmacokinetic		Paediatric Pharmacokinetic: Determination of pharmacokinetics of dalbavancin in paediatric patients aged 3 months through 11 years for selection of dosing in a Phase 3 therapeutic study for complicated skin and soft tissue infections.
	Pharmacokinetic		Paediatric Pharmacokinetic study: Determination of pharmacokinetics of dalbavancin in paediatric patients aged <3 months for selection of dosing in a Phase 3 therapeutic study for complicated skin and soft tissue infections.

	Efficacy and safety		Paediatric Safety and Efficacy study: Determination of safety and efficacy of dalbavancin in complicated skin and soft tissue infections in patients aged from 0 to less than 18 years of age requiring hospitalization and intravenous antibiotic therapy.

Need for paediatric measures in a EU-Risk Management Plan: Yes
Date of completion of the paediatric investigation plan: By 30 June 2011
A deferral has been granted: Yes