European Medicines Agency

Doc. Ref. EMEA/259268/2008
P/30/2008

EUROPEAN MEDICINES AGENCY DECISION

of 23 May 2008

on the application for modification of an agreed Paediatric Investigation Plan for Cancidas, caspofungin acetate, EMEA-000010-PIP01-07 MO1 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 decision no P/10/2008 of the European Medicines Agency on 29 February 2008,

Having regard to the application submitted by Merck Sharp & Dohme (Europe) Ltd on 2 May 2008 under Article 22 of Regulation (EC) No 1901/2006 as amended, for change to an agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, formulated on 8 May 2008, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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 a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the modification of an agreed Paediatric Investigation Plan.

[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 modification of an agreement of a Paediatric Investigation Plan concerning changes for Cancidas, caspofungin acetate, powder for concentrate for solution for infusion and 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 granted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency no P/10/2008 on identical matter, is addressed to Merck Sharp & Dohme (Europe) Ltd, Clos du Lynx 5, B-1200, Brussels, Belgium.

Done at London, 23 May 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/259268/2008
EMEA-000010-PIP01-07 MO1

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON MODIFICATION OF THE PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Caspofungin acetate

Invented name
Cancidas

Condition(s):
Fungal infections

Pharmaceutical form(s):
(1) Powder for concentrate for solution for infusion
(2) Powder for solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Merck Sharp & Dohme (Europe) Ltd

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Ltd submitted to the EMEA on 2 May 2008 an application for modification of the agreed paediatric investigation plan as set out in the EMEA decision P/10/2008 of 29 February 2008.

The procedure started on 6 May 2008.

Scope of the modification

The applicant proposed modifications to the agreed PIP to improve the clarity of the agreed measures.

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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 the modification of the paediatric investigation plan.

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 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 and appendix(ces).

London, 8 May 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. CONDITIONS / DISEASES

Fungal infections

B. WAIVER

Not applicable

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Conditions to be investigated

Fungal infections

- **Subset(s) covered**

All age subsets of the paediatric population

- **Formulation(s)**

No development needed in addition to the authorised formulations: Powder for concentrate for solution for infusion and Powder for solution for infusion

- **Studies / Measures**

Area	Subarea	Number	Description
Non-clinical	Juvenile toxicity	2	Nonclinical study to assess caspofungin pharmacokinetics, pharmacodynamics, and efficacy in juvenile rodent model of disseminated candidiasis. Five-week intravenous toxicity study in infant rhesus macaques
Clinical	Pharmacokinetics	3	Pharmacokinetic Study in Children & Adolescents (2-17 Years of Age) with new onset fever and neutropenia Pharmacokinetic Study in Infants 3-24 Months of Age Pharmacokinetic Study in Neonates & Young Infants <3 Months of Age Study
Clinical	Efficacy/safety	2	Prospective, randomized, double-blind study (vs. liposomal amphotericin B) examining the safety, tolerability, and efficacy of caspofungin as empirical therapy against presumed invasive fungal infections in pediatric patients (ages 2-17 years) with persistent fever and neutropenia Study against Documented *Candida* & *Aspergillus* Infections in Pediatric Patients 3 Months to 17 Years of Age

Need for paediatric measures in a EU-Risk Management Plan: Yes
Date of completion of the paediatric investigation plan: August 2007
A deferral has been granted*:* No