EMA/244166/2011

# European Medicines Agency decision

P/75/2011

of 5 April 2011

on the acceptance of a modification of an agreed paediatric investigation plan for anidulafungin (Ecalta), (EMEA-000469-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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# European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for anidulafungin (Ecalta), (EMEA-000469-PIP01-08-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/45/2010 issued on 31 March 2010, and decision P/201/2010 issued on 27 October 2010,

Having regard to the application submitted by Pfizer Limited on 6 December 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 February 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

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 on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision on the granting of 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***

Changes to the agreed paediatric investigation plan for anidulafungin (Ecalta), powder and solvent for concentrate for solution for infusion, powder for concentrate for solution for infusion, intravenous use, 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***

A deferral for anidulafungin (Ecalta), powder and solvent for concentrate for solution for infusion, powder for concentrate 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, United Kingdom.

Done at London, 5 April 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/804446/2010

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

EMEA-000469-PIP01-08-M02

## Scope of the application

**Active substance(s):**

Anidulafungin

**Invented name:**

Ecalta

**Condition(s):**

Treatment of invasive candidiasis

Treatment of invasive aspergillosis

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Powder and solvent for concentrate for solution for infusion

Powder for concentrate for solution for infusion

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

Pfizer Limited

**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, Pfizer Limited submitted to the European Medicines Agency on 6 December 2010 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/45/2010 issued on 31 March 2010, and the decision P/201/2010 issued on 27 October 2010. The application for modification proposed changes to the agreed paediatric investigation plan and proposed a deferral.

The procedure started on 22 December 2010.

## Scope of the modification

Some measures and timelines of the original Opinion have been modified and a deferral has been added.

## 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 in the scope set out in the Annex I of this opinion,
   - to grant a deferral, the details of which are set out in the Annex I of this opinion.

   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 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.

London, 18 February 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

# 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

# 1. Conditions

Treatment of invasive candidiasis

Treatment of invasive aspergillosis

# 2. Waiver

## *2.1. Condition*

Treatment of invasive candidiasis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

## *2.2. Condition*

Treatment of Invasive aspergillosis

The waiver applies to:

- The paediatric population from birth to less than 24 months of age;
- for
  - powder and solvent for concentrate for solution for infusion, intravenous use, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments,
  - powder for concentrate for solution for infusion, intravenous use, on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population;
- children 2 years to less than 18 years of age;
- for powder and solvent for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

# 3. Paediatric Investigation Plan

## *3.1. Condition to be investigated*

Invasive candidiasis

### 3.1.1. Indication targeted by the PIP

Treatment of invasive candidiasis

### 3.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

### 3.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

### 3.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | | Age appropriate presentation |
| Non-clinical | 3 | 1. Distribution of anidulafungin in brain, heart, and bone tissues in juvenile rats<br>2. Juvenile toxicology study of anidulafungin in rats<br>3. PK/PD study in rabbit haematogenous Candida meningoencephalitis model |
| Clinical | 3 | 4. Pharmacokinetic study of anidulafungin at standard dosing regimen in neonates, infants and toddlers less than 24 months<br>5. Pharmacokinetic study of anidulafungin at higher dosing regimens in neonates<br>6. Open-label trial to assess the pharmacokinetics, safety and efficacy of anidulafungin to treat children from one month to less than 18 years of age with invasive candidiasis |

## *3.2. Condition to be investigated:*

Invasive aspergillosis

### 3.2.1. Indication targeted by the pip

Voriconazole in combination with anidulafungin for the treatment of invasive aspergillosis in children from 2 to 18 years.

### 3.2.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 years to less than 18 years of age.

### 3.2.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

### 3.2.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | | Age appropriate presentation |
| Non-clinical | 1 | 1. 5 week single compound and combination toxicology study in juvenile rats with a 4 week recovery period. |
| Clinical | 1 | 1. Randomized, multi-centre trial to assess the safety, tolerability, and efficacy of voriconazole plus anidulafungin in combination to that of voriconazole monotherapy for treatment of invasive aspergillosis in patients 2 years to less than 18 years of age. |

## 4. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Measures to address long term follow-up of potential safety issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By October 2013 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

# Condition(s) and authorised indication(s)

Treatment of invasive candidiasis

**Authorised indication:**

Treatment of invasive candidiasis in adult non-neutropenic patients.

| EU Number | Invented name | Strength | Pharmaceutical Form | Route of Administration | Packaging | Content | Package size |
|---|---|---|---|---|---|---|---|
| EU/1/07/416/001 | ECALTA | 100 mg | Powder and solvent for concentrate for solution for infusion | Intravenous use | powder: vial (glass); solvent: vial (glass) | 100mg; 30 ml | 1 vial + 1 vial |
| EU/1/07/416/002 | ECALTA | 100 mg | Powder for concentrate for solution for infusion | Intravenous use | vial (glass) | 100 mg | 1 vial |