EMA/90864/2017

European Medicines Agency decision

P/0053/2017

of 17 March 2017

on the acceptance of a modification of an agreed paediatric investigation plan for anidulafungin (Ecalta), (EMEA-000469-PIP01-08-M07) 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/45/2010 issued on 31 March 2010, the decision P/201/2010 issued on 27 October 2010, the decision P/75/2011 issued on 5 April 2011, the decision P/297/2011 issued on 20 December 2011, the decision P/0091/2015 issued on 8 May 2015 and the decision P/0208/2016 issued on 12 August 2016,

Having regard to the application submitted by Pfizer Limited on 2 November 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 27 January 2017, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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

Changes to the agreed paediatric investigation plan for anidulafungin (Ecalta), 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

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

EMA/PDCO/735869/2016
London, 27 January 2017

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

EMEA-000469-PIP01-08-M07

Scope of the application

Active substance(s):

Anidulafungin

Invented name:

Ecalta

Condition(s):

Treatment of invasive candidiasis

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:

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 2 November 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/45/2010 issued on 31 March 2010, the decision P/201/2010 issued on 27 October 2010, the decision P/75/2011 issued on 5 April 2011, the decision P/297/2011 issued on 20 December 2011, the decision P/0091/2015 issued on 8 May 2015 and the decision P/0208/2016 issued on 12 August 2016.

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

The procedure started on 29 November 2016.

Scope of the modification

Some measures 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 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 invasive candidiasis

The waiver applies to:

- the paediatric population from birth to 1 month 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 invasive candidiasis

2.1.1. Indication targeted by the PIP

Treatment of invasive candidiasis

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

From 1 month to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	**Study 1** Deleted (procedure EMEA-000469-PIP01-08-M07)
Non-clinical studies	3	**Study 2** Tissue distribution study in juvenile rats **Study 3** Juvenile toxicology study of anidulafungin in rats **Study 4** PK/PD study in rabbit haematogenous Candida meningoencephalitis model

Clinical studies	2	**Study 5** Pharmacokinetic study of anidulafungin at standard dosing regimen in neonates, infants and toddlers less than 24 months **Study 6** Deleted (procedure EMEA-000469-PIP01-08-M05) **Study 7** 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
Extrapolation, modelling and simulation studies		Not applicable.
Other studies		Not applicable.
Other measures		Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2019
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):

1. Treatment of invasive candidiasis

Authorised indication(s):

- Treatment of invasive candidiasis in adult patients.

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use