EMA/757016/2010

European Medicines Agency decision

P/272/2010

of 29 November 2010

on the acceptance of a modification of an agreed paediatric investigation plan for eritoran (EMEA-000509-PIP02-09-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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on the acceptance of a modification of an agreed paediatric investigation plan for eritoran (EMEA-000509-PIP02-09-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/56/2010 issued on 31 March 2010 and the decision P/190/2010 issued on 30 September 2010,

Having regard to the application submitted by Eisai Limited on 4 October 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 November 2010, 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 eritoran, powder and solvent 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 Eisai Limited, European Knowledge Centre, Mosquito Way, European Knowledge Centre, Mosquito Way, AL10 9SN, Hatfield, Hertfordshire, United Kingdom.

Done at London, 29 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

EMA/PDCO/654590/2010

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

EMA-000509-PIP02-09-M02

Scope of the application

Active substance(s):

Eritoran

Condition(s):

Sepsis

Pharmaceutical form(s):

Powder and solvent for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Eisai Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eisai Limited submitted to the European Medicines Agency on 04 October 2010 an application for modification of the agreed paediatric investigation plan with a deferral, as set out in the European Medicines Agency's decision P/56/2010 issued on 31 March 2010 and the decision P/190/2010 issued on 30 September 2010.

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

The procedure started on 13 October 2010.

Scope of the modification

The scope of the modification was to change the date of initiation of phase I trial E5564-G000-103.

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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 to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   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 paediatric investigation plan 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 annex(es) and appendix.

London, 12 November 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

Annex I

The measures and timelines of the agreed Paediatric Investigation Plan and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Sepsis

2. Waiver

Not applicable

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Sepsis

3.1.1. Indication(s) targeted by the PIP

Treatment of severe sepsis

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)

Eritoran 7 mg/vial

3.1.4. Studies

Area	Number of studies	Description
Quality	1	1. Compatibility testing of eritoran with medicines frequently used in the treatment of sepsis
Non-clinical	4	2. Pharmacokinetics of Eritoran in pregnant rats 3. Pharmacokinetics of Eritoran in lactating rats 4. 4-week toxicity study in juvenile rats (1 week of age) 5. 4-week toxicity study in juvenile rats (5 weeks of age)
Clinical	2	6. Safety and pharmacokinetics, open label multiple dose trial with sequential descending age-based cohorts to characterise the pharmacokinetic and pharmacodynamic of eritoran in paediatric severe sepsis 7. Efficacy and safety, randomised double-blind, placebo-controlled parallel group trial to demonstrate that eritoran treatment of paediatric subjects with severe sepsis results in a reduction in the Composite Time to Complete Organ Failure Resolution (CTCOFR)

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	by November 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes