EMA/313498/2013

European Medicines Agency decision

P/0134/2013

of 14 June 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral for isavuconazonium (sulfate) (EMEA-001301-PIP01-12) 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 application submitted by Astellas Pharma Europe B.V. on 2 July 2012 under Article 16(1) of Regulation (EC) No 1901/2006 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 17 May 2013, in accordance with Article 18 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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a 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 isavuconazonium (sulfate), powder for solution for infusion, capsule, hard, intravenous use, oral 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 isavuconazonium (sulfate), powder for solution for infusion, capsule, hard, intravenous use, oral 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 3

This decision is addressed to Astellas Pharma Europe B.V., 62 Sylviusweg, 2333 BE – Leiden, The Netherlands.

Done at London, 14 June 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/313498/2013

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001301-PIP01-12

Scope of the application

Active substance(s):

Isavuconazonium (sulfate)

Condition(s):

Treatment of Candida infections

Pharmaceutical form(s):

Powder for solution for infusion

Capsule, hard

Route(s) of administration:

Intravenous use

Oral use

Name/corporate name of the PIP applicant:

Astellas Pharma Europe B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe B.V. submitted for agreement to the European Medicines Agency on 2 July 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 9 August 2012.

Supplementary information was provided by the applicant on 21 February 2013. The applicant proposed modifications to the paediatric investigation plan.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   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 European Medicines Agency, together with its annex and appendix.

London, 17 May 2013

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. Waiver

Not applicable.

2. Paediatric Investigation Plan

– ***Condition: Treatment of Candida infections***

2.1.1. Indication(s) targeted by the PIP

Primary treatment of invasive candidiasis/candidemia

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for infusion.

Capsule, hard.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	
Non-clinical	1	Measure 1: 9766-TX-0066 Thirteen-week, oral gavage repeated-dose study to evaluate safety and toxicokinetics in four groups of juvenile rats treated with isavuconazonium (sulphate) followed by a 4-week recovery period.
Clinical	4	Measure 2: 9766-CL-0046 Open-label, multi-center, noncomparative study to evaluate pharmacokinetics and safety of intravenous isavuconazonium (sulfate) in children from 4 months to less than 18 years of age with haematologic malignancy. Measure 3: 9766-CL-0047 Open-label, multi-centre, noncomparative study to evaluate pharmacokinetics and safety of intravenous isavuconazonium (sulfate) in children who are preterm newborns to less than 4 months old with known or suspected invasive candidiasis/candidemia. Measure 4: 9766-CL-0048 Open-label, multi-center, multiple-dose, noncomparative study to evaluate pharmacokinetics and safety of oral isavuconazonium (sulfate) in children from 6 to less than 18 years of age with haematologic malignancy.

Area	Number of measures	Description
		Measure 5: 9766-CL-0108 Open-label, multi-center, noncomparative study to evaluate safety and tolerability of isavuconazonium (sulfate) in children from birth to less than 18 years of age with invasive candidiasis/candidemia or esophageal candidiasis.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By December 2020.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.