EMA/293458/2017

European Medicines Agency decision

P/0151/2017

of 7 June 2017

on the acceptance of a modification of an agreed paediatric investigation plan for isavuconazonium (sulfate), (Cresemba) (EMEA-001301-PIP02-12-M01) 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/0135/2013 issued on 14 June 2013,

Having regard to the application submitted by Basilea Pharmaceutica International Ltd. on 26 January 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver.

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 April 2017, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 13 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 to the deferral and on the granting of a waiver.

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

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

[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 isavuconazonium (sulfate), (Cresemba), powder for solution for infusion, capsule, hard, intravenous use, oral use including changes to the deferral, 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 waiver for isavuconazonium (sulfate), (Cresemba), 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 the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Basilea Pharmaceutica International Ltd., Grenzacherstrasse 487, 4005 - Basel, Switzerland.

EMA/PDCO/111034/2017
London, 21 April 2017

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

EMEA-001301-PIP02-12-M01

Scope of the application

Active substance(s):

Isavuconazonium (sulfate)

Invented name:

Cresemba

Condition(s):

Treatment of invasive aspergillosis

Treatment of mucormycosis

Authorised indication(s):

See Annex II

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:

Basilea Pharmaceutica International Ltd.

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, Basilea Pharmaceutica International Ltd. submitted to the European Medicines Agency on 26 January 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0135/2013 issued on 14 June 2013.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver.

The procedure started on 21 February 2017.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset 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 and to the deferral;
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 aspergillosis

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- powder for solution for infusion, capsule, hard; intravenous use, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition:

Treatment of mucormycosis

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- powder for solution for infusion, capsule, hard; intravenous use, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of invasive aspergillosis

2.1.1. Indication(s) targeted by the PIP

Treatment of invasive aspergillosis

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

From 1 year 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 (sulfate) followed by a 4-week recovery period
Clinical	3	Measure 2: 9766-CL-0046 Open-label, multi-center, noncomparative study to evaluate pharmacokinetics and safety of intravenous isavuconazonium (sulfate) in children from 1 year to less than 18 years of age with haematologic malignancy Measure 3: 9766-CL-0047 Study deleted in modification EMEA-001301-PIP02-12-M01. 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 Measure 5: 9766-CL-0107 Open-label, multi-center, noncomparative study to evaluate safety and tolerability of isavuconazonium (sulfate) in children from 1 year to less than 18 years of age with invasive aspergillosis and infections caused by rare moulds and yeasts (e.g., zygomycetes/mucormycetes, non-candida yeasts or dimorphic fungi)

2.2. Condition: Treatment of mucormycosis

2.2.1. Indication(s) targeted by the PIP

Treatment of mucormycosis

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

From 1 year to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Powder for solution for infusion

Capsule, hard

2.2.4. Measures

Area	Number of measures	Description
Quality	0	
Non-clinical	1	Measure 1 Same measure as for condition Treatment of invasive aspergillosis.
Clinical	3	Measure 2 Same measure as for condition Treatment of invasive aspergillosis. Measure 3 Study deleted in modification EMEA-001301-PIP02-12-M01. Measure 4 Same measure as for condition Treatment of invasive aspergillosis. Measure 5 Same measure as for condition Treatment of invasive aspergillosis.

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 2021
Deferral for one or more measures 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 aspergillosis

Authorised indication(s):

Cresemba is indicated in adults for the treatment of invasive aspergillosis.

2. Treatment of mucormycosis

Authorised indication(s):

Cresemba is indicated in adults for the treatment of mucormycosis in patients for whom amphotericin B is inappropriate.

Authorised pharmaceutical form(s):

Capsule, hard

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Oral use

Intravenous use