EMA/202226/2013

# European Medicines Agency decision

P/0096/2013

of 29 April 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral for surotomycin (EMEA-001226-PIP01-11) 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 Cubist Pharmaceuticals, Inc. on 10 April 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation, and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 March 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 surotomycin, tablet, age-appropriate oral solid formulation, 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 surotomycin, tablet, age-appropriate oral solid formulation, 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 Cubist Pharmaceuticals, Inc., 65 Hayden Avenue, MA 02421 – Lexington, United States.

Done at London, 29 April 2013

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

EMA/PDCO/818425/2012

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

EMEA-001226-PIP01-11

## Scope of the application

**Active substance(s):**

Surotomycin

**Condition(s):**

Treatment of clostridia infections

**Pharmaceutical form(s):**

Tablet

Age-appropriate oral solid formulation

**Route(s) of administration:**

Oral use

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

Cubist Pharmaceuticals, Inc.

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Cubist Pharmaceuticals, Inc. submitted for agreement to the European Medicines Agency on 10 April 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 May 2012.

Supplementary information was provided by the applicant on 17 December 2012. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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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 Norwegian Paediatric Committee member agrees 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, 15 March 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

## *2.1. Condition: treatment of clostridia infections*

### 2.1.1. Indication(s) targeted by the PIP

Treatment of clostridium difficile associated diarrhoea

### 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)

Tablet

Age-appropriate oral solid formulation

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality | 1 | **Measure 1**<br>Development of an age-appropriate oral solid formulation that can be dispersed or dissolved. |
| Non-clinical | 3 | **Measure 2**<br>Single-dose subcutaneous pharmacokinetic study in juvenile dogs.<br>**Measure 3**<br>14-day subcutaneous dose ranging study including toxicokinetics in juvenile dogs.<br>**Measure 4**<br>1-month subcutaneous toxicity study in juvenile dogs. |
| Clinical | 2 | **Measure 5**<br>Open-label, multiple dose trial to evaluate safety and pharmacokinetics of surotomycin in children from birth to less than 18 years of age with C. difficile infection.<br>**Measure 6**<br>Evaluator-blinded, randomised, multiple dose, active controlled trial to evaluate safety and tolerability of surotomycin in children from birth to less than 18 years of age with C. difficile infection. |

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

| | |
|---|---|
| Concerns on potential long term efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By September 2020 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |