EMA/710289/2012

European Medicines Agency decision

P/0280/2012

of 21 November 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral for tazobactam / ceftolozane (EMEA-001142-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

European Medicines Agency decision

P/0280/2012

of 21 November 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral for tazobactam / ceftolozane (EMEA-001142-PIP01-11) 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 application submitted by Cubist Pharmaceuticals, Inc. on 5 December 2011 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 5 October 2012, 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 tazobactam / ceftolozane, powder for solution for infusion, intravenous 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 tazobactam / ceftolozane, powder for solution for infusion, intravenous 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, 21 November 2012

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

EMA/PDCO/121119/2012

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

EMEA-001142-PIP01-11

Scope of the application

Active substance(s):

Tazobactam / ceftolozane

Condition(s):

Treatment of urinary tract infections

Treatment of abdominal and gastrointestinal infections

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous 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 5 December 2011 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 12 January 2012.

Supplementary information was provided by the applicant on 16 July 2012. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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 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 annex and appendix.

London, 5 October 2012

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 urinary tract infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated urinary tract infections (cUTI).

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.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	3	Study 1 Single dose pharmacokinetic study in juvenile rats. Study 2 14-day dose ranging toxicity study in juvenile rats. Study 3 28-day toxicity study in juvenile rats.
Clinical	2	Study 4 Open-label, single dose trial to evaluate pharmacokinetics of tazobactam / ceftolozane in children from birth to less than 18 years of age with proven or suspected Gram-negative infection receiving standard antibiotic therapy. Study 5 Double blind, randomised, active controlled trial to evaluate safety, tolerability and efficacy of tazobactam / ceftolozane in children from birth to less than 18 years of age with complicated urinary tract infection (cUTI).

2.2. Condition: treatment of abdominal and gastrointestinal infections

2.2.1. Indication(s) targeted by the PIP

Treatment of complicated intra-abdominal infections (cIAI).

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Powder for solution for infusion.

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	3	Study 1 Single dose pharmacokinetic study in juvenile rats. (Same study as for condition 'Treatment of urinary tract infections') Study 2 14-day dose ranging toxicity study in juvenile rats. (Same study as for condition 'Treatment of urinary tract infections') Study 3 28-day toxicity study in juvenile rats. (Same study as for condition 'Treatment of urinary tract infections')
Clinical	2	Study 4 Open-label, single dose trial to evaluate pharmacokinetics of tazobactam / ceftolozane in children from birth to less than 18 years of age with proven or suspected Gram-negative infection receiving standard antibiotic therapy. (Same study as for condition 'Treatment of urinary tract infections') Study 6 Double blind, randomised, active controlled trial to evaluate safety, tolerability and efficacy of tazobactam / ceftolozane in children from birth to less than 18 years of age with complicated intra-abdominal infection (cIAI).

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 June 2021.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.