



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/585513/2013

European Medicines Agency decision

P/0249/2013

of 18 October 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral for tedizolid (phosphate) (EMEA-001379-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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Trius Therapeutics Inc. on 10 December 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 13 September 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 tedizolid (phosphate), film-coated tablet, powder for concentrate for solution for infusion, powder for oral suspension, oral use, 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 tedizolid (phosphate), film-coated tablet, powder for concentrate for solution for infusion, powder for oral suspension, oral use, 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 Trius Therapeutics Inc., 6310 Nancy Ridge Drive, Ste 105, CA 92121 - San Diego, United States.

Done at London, 18 October 2013

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

EMA/PDCO/388212/2013 **Corr**

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

EMA-001379-PIP01-12

Scope of the application

Active substance(s):

Tedizolid (phosphate)

Condition(s):

Treatment of complicated skin and soft tissue infections

Pharmaceutical form(s):

Film-coated tablet

Powder for concentrate for solution for infusion

Powder for oral suspension

Route(s) of administration:

Oral use

Intravenous use

Name / corporate name of the PIP applicant:

Trius Therapeutics Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Trius Therapeutics Inc. submitted for agreement to the European Medicines Agency on 10 December 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 16 January 2013.

Supplementary information was provided by the applicant on 24 June 2013. The applicant proposed modifications to the paediatric investigation plan.

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, 13 September 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 complicated skin and soft tissue infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated skin and soft tissue infections

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)

Film-coated tablet

Powder for oral suspension

Powder for concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality	2	1. Development of an age appropriate oral formulation (Powder for oral suspension) 2. Development of an age appropriate presentation of the powder for concentrate for solution for infusion for use in the paediatric population less than 3 months
Non-clinical	2	3. Dose-range finding study in juvenile rats 4. Subacute toxicity study in juvenile rats
Clinical	5	5. Single-Dose trial to evaluate pharmacokinetics and safety of oral and intra-venous (iv) administration of tedizolid phosphate (TR-701 FA) in patients less than 2 years of age (TR701-121) 6. Single-Dose trial to evaluate pharmacokinetics and safety of oral and intra-venous (iv) administration of tedizolid phosphate (TR-701 FA) in patients 2 years to less than 12 years of age (TR701-120) 7. Randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients 12 to less than 18 years of age (TR701-122)

Area	Number of measures	Description
		8. Randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients 3 months to less than 12 years of age (TR701-128) 9. Open-label, multicentre study to evaluate the pharmacokinetics and safety of intravenous tedizolid phosphate in neonates and infants less than three months of age with late onset sepsis (TR701-129).

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 February 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes