



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/576579/2016

European Medicines Agency decision

P/0264/2016

of 5 October 2016

on the acceptance of a modification of an agreed paediatric investigation plan for tedizolid (phosphate) (Sivextro), (EMA-001379-PIP01-12-M02) 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 European Medicines Agency's decision P/0249/2013 issued on 18 October 2013 and the decision P/0258/2014 issued on 1 October 2014,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 30 May 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 August 2016, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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.
- (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.

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 tedizolid (phosphate) (Sivextro), film-coated tablet, powder for concentrate for solution for infusion, powder for oral suspension, oral use, intravenous 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

This decision is addressed to Merck Sharp & Dohme (Europe), Inc., Lynx binnenhof 5, 1200 - Brussels, Belgium.

EMA/PDCO/387880/2016
London, 19 August 2016

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001379-PIP01-12-M02

Scope of the application

Active substance(s):

Tedizolid (phosphate)

Invented name:

Sivextro

Condition(s):

Treatment of acute bacterial skin and skin structure infections

Authorised indication(s):

See Annex II

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:

Merck Sharp & Dohme (Europe), Inc.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted to the European Medicines Agency on 30 May 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0249/2013 issued on 18 October 2013 and the decision P/0258/2014 issued on 1 October 2014.

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

The procedure started on 21 June 2016.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 in the scope set out in the Annex I of this opinion.

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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of acute bacterial skin and skin structure infections

2.1.1. Indication(s) targeted by the PIP

Treatment of acute bacterial skin and skin structure 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-related studies	2	Study 1 Development of an age appropriate oral formulation (Powder for oral suspension) Study 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 of age

Area	Number of measures	Description
Non-clinical studies	3	Study 3 Dose-range finding study in juvenile rats Study 4 Subacute toxicity study in juvenile rats Study 5 Subacute toxicity study in juvenile Long Evans rats to assess neurotoxicity of tedizolid phosphate
Clinical studies	5	Study 6 Single-Dose trial to evaluate pharmacokinetics and safety of oral and intra-venous (iv) administration of tedizolid phosphate in patients less than 2 years of age (MK-1986-014) Study 7 Single-Dose trial to evaluate pharmacokinetics and safety of oral and intra-venous (iv) administration of tedizolid phosphate in patients 2 years to less than 12 years of age (MK-1986-013) Study 8 Randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients 12 to less than 18 years of age (MK-1986-012) Study 9 Randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients 3 months to less than 12 years of age (MK-1986-018) Study 10 Open-label, multicentre studies to evaluate the pharmacokinetics and safety of intravenous tedizolid phosphate in neonates and infants less than three months of age with late onset sepsis (MK-1986-021).
Extrapolation, modelling and simulation studies		Not applicable.
Other studies		Not applicable.
Other measures		Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2020
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 acute bacterial skin and skin structure infections

Authorised indication(s):

- Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults

Authorised pharmaceutical form(s):

Film-coated tablet

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Oral use

Intravenous use