EMA/576890/2020

European Medicines Agency decision

P/0462/2020

of 1 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for tedizolid (phosphate) (Sivextro), (EMEA-001379-PIP01-12-M05) 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/0249/2013 issued on 18 October 2013, the decision P/0258/2014 issued on 1 October 2014, the decision P/0264/2016 issued on 5 October 2016, the decision P/0031/2018 on 30 January 2018 and the decision P/0226/2019 issued on 5 July 2019,

Having regard to the application submitted by , Merck Sharp & Dohme (Europe), Inc. on 9 July 2020 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 16 October 2020, 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., Clos du Lynx/Lynx Binnenhof, 5, 1200 - Brussels, Belgium.

EMA/PDCO/417753/2020
Amsterdam, 16 October 2020

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

EMEA-001379-PIP01-12-M05

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 9 July 2020 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, the decision P/0258/2014 issued on 1 October 2014, the decision P/0264/2016 issued on 5 October 2016, the decision P/0031/2018 on 30 January 2018 and the decision P/0226/2019 issued on 5 July 2019.

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

The procedure started on 18 August 2020.

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) for children under 12 years of age. **Study 2** Development of an age appropriate method of administration of the powder for concentrate for solution for infusion for use in paediatric patients under 12 months of age
Non-clinical studies	3	**Study 3** Dose-range finding study in juvenile rats (TE.701.TX.001) **Study 4** Subacute toxicity study in juvenile rats (TE.701.TX.002) **Study 5** Subacute toxicity study in juvenile Long Evans rats to assess neurotoxicity of tedizolid phosphate (TE.701.TX.003)

Clinical studies	4	**Study 6** Open-label, multicentre, 2-part, single and multiple dose study to assess the pharmacokinetics (PK) of tedizolid phosphate and its active metabolite, tedizolid, and the safety of tedizolid phosphate following administration of a single dose and multiple doses IV, and single oral dose. (MK-1986-014) **Study 7** Single-Dose trial to evaluate pharmacokinetics and safety of oral and intravenous (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 from birth to less than 12 years of age (MK-1986-018)
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 December 2022
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