EMA/103715/2023

European Medicines Agency decision

P/0112/2023

of 13 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for tedizolid (phosphate) (Sivextro), (EMEA-001379-PIP01-12-M07) 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 Union procedures for the authorisation and supervision of medicinal products for human 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, decision P/0258/2014 issued on 1 October 2014, decision P/0264/2016 issued on 5 October 2016, decision P/0031/2018 on 30 January 2018, decision P/0226/2019 issued on 5 July 2019, decision P/0462/2020 issued on 1 December 2020. and the decision P/0050/2022 issued on 24 February 2022,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 18 November 2022 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 24 February 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

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/912135/2022
Amsterdam, 24 February 2023

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

EMEA-001379-PIP01-12-M07

Scope of the application

Active substance(s):

Tedizolid (phosphate)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acute bacterial skin and skin structure 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:

Merck Sharp & Dohme (Europe), Inc.

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 18 November 2022 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, decision P/0258/2014 issued on 1 October 2014, decision P/0264/2016 issued on 5 October 2016, decision P/0031/2018 on 30 January 2018,

decision P/0226/2019 issued on 5 July 2019, decision P/0462/2020 issued on 1 December 2020 and the decision P/0050/2022 issued on 24 February 2022.

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

The procedure started on 3 January 2023.

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 Paediatric Committee member of Norway 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	Description
Quality-related studies	**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	**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	**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 June 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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 and adolescents 12 years of age and older.
  - Invented name(s): Sivextro
  - Authorised pharmaceutical form(s): Film-coated tablet, powder for concentrate for solution for infusion
  - Authorised route(s) of administration: Oral use, intravenous use
  - Authorised via centralised procedure