EMA/170204/2019

European Medicines Agency decision

P/0109/2019

of 22 March 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for ridinilazole (EMEA-002250-PIP02-17) 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 application submitted by Summit (Oxford) Limited on 27 November 2017 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 1 February 2019, in accordance with Article 17 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 ridinilazole, film-coated tablet, age-appropriate oral liquid dosage form, oral 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 ridinilazole, film-coated tablet, age-appropriate oral liquid dosage form, oral 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 Summit (Oxford) Limited, 136a Eastern Avenue, Milton Park, OX14 4SB - Abingdon, United Kingdom.

EMA/PDCO/799946/2018
London, 1 February 2019

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

EMEA-002250-PIP02-17

Scope of the application

Active substance(s):

Ridinilazole

Condition(s):

Treatment of Clostridium difficile Infection

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Summit (Oxford) Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Summit (Oxford) Limited submitted for agreement to the European Medicines Agency on 27 November 2017 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 3 January 2018.

Supplementary information was provided by the applicant on 29 October 2018. The applicant proposed modifications to the paediatric investigation plan.

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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 17(1) 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 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.

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.

1.1. Condition

Treatment of Clostridium difficile Infection (CDI)

2. Paediatric investigation plan

2.1. Condition

Treatment of Clostridium difficile Infection (CDI)

2.1.1. Indication(s) targeted by the PIP

Treatment of Clostridium difficile Infection (CDI)

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

Age-appropriate oral liquid dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1 (SMT19969-Q-116)** Development and evaluation of an age-appropriate oral formulation.
Non-clinical studies	1	**Study 2(SMT19969-N-137)** Juvenile toxicity study in rats to determine the no-observed-adverse-effect levels by IV and oral routes of administration and the associated toxicokinetic parameters.
Clinical studies	3	**Study 3(SMT19969/C006)** Randomised, double blind, active controlled study to evaluate the safety, tolerability and pharmacokinetics of ridinilazole compared with vancomycin in adolescents from 12 to less than 18 years of age with Clostridium difficile Infection (CDI). **Study 4 (SMT19969/C007)** Randomised, double blind, active-controlled study to evaluate the safety, tolerability and pharmacokinetics of ridinilazole compared with vancomycin in children from 2 to less than 12 years of age with CDI.

		Study 5 (SMT19969/C008) Open-label study to evaluate the pharmacokinetics, tolerability and safety of ridinilazole in children less than 2 years of age with CDI.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes