EMA/100334/2022

European Medicines Agency decision

P/0087/2022

of 11 March 2022

on the acceptance of a modification of an agreed paediatric investigation plan for ridinilazole (hydrate) (EMEA-002250-PIP02-17-M01) 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/0109/2019 issued on 22 March 2019,

Having regard to the application submitted by Summit Limited on 18 October 2021 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 21 January 2022, 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 ridinilazole (hydrate), film-coated tablet, age-appropriate oral formulation, oral 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 Summit Limited, 136a Eastern Avenue Milton, OX14 4 SB - Abingdon Oxfordshire, United Kingdom.

EMA/PDCO/603108/2021
Amsterdam, 21 January 2022

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

EMEA-002250-PIP02-17-M01

Scope of the application

Active substance(s):

Ridinilazole (hydrate)

Condition(s):

Treatment of *Clostridioides difficile* infection

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Summit Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Summit Limited submitted to the European Medicines Agency on 18 October 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0109/2019 issued on 22 March 2019.

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

The procedure started on 22 November 2021

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 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 *Clostridioides difficile* infection (CDI)

2. Paediatric investigation plan

2.1. Condition

Treatment of *Clostridioides difficile* infection (CDI)

2.1.1. Indication(s) targeted by the PIP

Treatment of *Clostridioides 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 formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1 (SMT19969-Q-116)** Development 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)** A randomised, double blind, active controlled study to evaluate the safety, tolerability and pharmacokinetics of ridinilazole compared with vancomycin in adolescents from 12 years to less than 18 years of age with Clostridioides difficile infection (CDI) **Study 4 (SMT19969/C007)** Randomised, open label, active-controlled study to evaluate the safety, tolerability and pharmacokinetics of ridinilazole

		compared with vancomycin in children from 2 years 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 October 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes