EMA/257454/2024

European Medicines Agency decision

P/0197/2024

of 13 June 2024

on the agreement of a paediatric investigation plan and on the refusal of a deferral and on the granting of a waiver for radiprodil (EMEA-003462-PIP01-23) 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 application submitted by GRIN Therapeutics, Inc. on 31 May 2023 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 April 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 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 refusal of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision refusing a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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

A paediatric investigation plan for radiprodil, oral suspension, oral use, nasogastric use, gastric 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 radiprodil, oral suspension, oral use, nasogastric use, gastric 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 refused.

Article 3

A waiver for radiprodil, oral suspension, oral use, nasogastric use, gastric 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 4

This decision is addressed to GRIN Therapeutics, Inc., 230 Park Avenue, Suite 2830, 10169 - New York, USA.

EMA/PDCO/63181/2024
Amsterdam, 26 April 2024

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

EMEA-003462-PIP01-23

Scope of the application

Active substance(s):

Radiprodil

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of GRIN-related disorder

Pharmaceutical form(s):

Oral suspension

Route(s) of administration:

Oral use

Nasogastric use

Gastric use

Name/corporate name of the PIP applicant:

GRIN Therapeutics, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GRIN Therapeutics, Inc. submitted for agreement to the European Medicines Agency on 31 May 2023 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 14 August 2023.

Supplementary information was provided by the applicant on 22 January 2024.

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 waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.
   - to refuse a deferral in accordance with Article 21 of said Regulation;

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

1.1. Condition:

Treatment of GRIN-related disorder

The waiver applies to:

- the infants from birth to less than one month of age;
- oral suspension; oral use, nasogastric use and gastric use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of GRIN-related disorder

2.1.1. Indication(s) targeted by the PIP

Treatment of GRIN-related disorder

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From one month to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral suspension

2.1.4. Measures

Area	Description
Quality-related studies	***Study 1*** A quality study to evaluate the compatibility of the product with the devices to be used in the clinical studies
Non-clinical studies	Not applicable
Clinical studies	***Study 2 (RAD-GRIN-101)*** Open-label, non-comparative, multiple individually titrated doses trial to evaluate pharmacokinetics, safety and activity of radiprodil as an add-on therapy to standard of care (SOC) in children from 6 months to less than 13 years of age with GRIN-related disorders

	Study 3 Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of radiprodil in children from 1 month to 12 years of age with GRIN-related disorder ***Study 4*** Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, efficacy and safety of radiprodil in patients from 12 to 17 years of age with GRIN-related disorder
Modelling and simulation analyses	***Study 5*** Modelling and simulation analyses population PK study, to evaluate the use of the product in children from 1 month to less than 18 years of age with GRIN-related disorder
Other studies	Not applicable
Extrapolation plan	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 April 2028
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.