EMA/554255/2024

European Medicines Agency decision

P/0392/2024

of 6 December 2024

on the agreement of a paediatric investigation plan and on the granting of a deferral for linaprazan glurate (EMEA-003558-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 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 Cinclus Pharma Holding AB on 15 December 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 18 October 2024, 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 linaprazan glurate, tablet, granules, 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 linaprazan glurate, tablet, granules, 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 Cinclus Pharma Holding AB, 1 Kungsbron, plan 3, trappa G, 11122 – Stockholm, Sweden.

EMA/PDCO/329339/2024
Amsterdam, 18 October 2024

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

EMEA-003558-PIP01-23

Scope of the application

Active substance(s):

Linaprazan glurate

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of gastro-oesophageal reflux disease

Pharmaceutical form(s):

Tablet

Granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Cinclus Pharma Holding AB

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Cinclus Pharma Holding AB submitted for agreement to the European Medicines Agency on 15 December 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 22 January 2024.

Supplementary information was provided by the applicant on 26 June 2024. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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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 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 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 gastro-oesophageal reflux disease

2.1.1. Indication(s) targeted by the PIP

Treatment of erosive oesophagitis due to gastro-oesophageal reflux disease (GORD)

Long-term management of patients with healed oesophagitis to prevent relapse

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)

Tablet

Granules

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1:** Development of an age-appropriate oral solid dosage form (granules)
Non-clinical studies	Not applicable
Clinical studies	**Study 2:** Open label, single arm study to assess pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability after single and multiple doses of linaprazan glurate in paediatric patients from 12 years to less than 18 years of age with gastroesophageal reflux disease (GORD) **Study 3:** Open label, single arm study to assess pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability after multiple doses of linaprazan glurate in paediatric patients from birth to less than 12 years of age with gastroesophageal reflux disease

	Study 4: Open-label healing period trial followed by a double-blind, randomised, placebo-controlled maintenance period trial to evaluate efficacy and safety of linaprazan glurate in paediatric patients from birth to less than 18 years of age with erosive esophagitis due to gastroesophageal reflux disease to estimate treatment effects.
Modelling and simulation analyses	**Study 5:** Modelling and simulation analyses (population PK) to predict initial paediatric doses and to confirm or modify the paediatric posology
Other studies	Not applicable
Extrapolation plan	Studies 2, 3, 4 and 5 are part of the extrapolation plan of efficacy data from adult patients to the paediatric population from birth to less than 18 years of age with gastro-oesophageal reflux disease.

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 February 2036
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:

The product is not authorised anywhere in the European Community.