EMA/776153/2022

European Medicines Agency decision

P/0458/2022

of 28 October 2022

on the acceptance of a modification of an agreed paediatric investigation plan for insulin human (NTRA-2112/ELGN-2112) (EMEA-002116-PIP01-17-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/0079/2018 issued on 16 March 2018,

Having regard to the application submitted by ELGAN Pharma Ltd on 12 May 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 September 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 insulin human (NTRA-2112/ELGN-2112), powder for oral solution, 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 ELGAN Pharma Ltd, 13 Wadi El Haj, 13 – Nazareth, Israel.

EMA/PDCO/567236/2022
Amsterdam, 9 September 2022

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

EMEA-002116-PIP01-17-M01

Scope of the application

Active substance(s):

Insulin human (NTRA-2112/ELGN-2112)

Condition(s):

Treatment of intestinal malabsorption in preterm infants

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ELGAN Pharma Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ELGAN Pharma Ltd submitted to the European Medicines Agency on 12 May 2022 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0079/2018 issued on 16 March 2018.

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

The procedure started on 11 July 2022.

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 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 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

1.1. Condition:

Treatment of intestinal malabsorption in preterm infants

The waiver applies to:

- the paediatric population from 32 weeks gestation to less than 18 years;
- powder for oral solution, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of intestinal malabsorption in preterm infants

2.1.1. Indication(s) targeted by the PIP

Treatment of intestinal malabsorption in preterm infants

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

Premature infants below 32 weeks gestation

2.1.3. Pharmaceutical form(s)

Powder for oral solution

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Multi-centre, double-blind, randomised, three-arm, parallel-group, placebo controlled study (with a pharmacodynamic sub-study) to assess the efficacy and safety of two doses of NTRA-2112 on intestinal malabsorption in preterm infants born between 26 and 32 weeks gestational age. (FIT-04)

	Study 2 Multi-centre, double-blind, randomised, two-arm, parallel-group, placebo controlled study to assess the safety of ELGN-2112 in preterm infants born under 26 weeks gestational age (GA) and Intra-Uterine Growth Restricted (IUGR) infants born 26-32 weeks GA. (FIT-05) **Study 3 (new study added in procedure EMEA-002116-PIP01-17-M01)** Multi-centre, double-blind, randomised, two-arm, parallel-group, placebo-controlled study to assess the efficacy and safety of ELGN-2112 on intestinal malabsorption in preterm infants from 26 to less than 32 weeks GA and a birth weight above 500g. (FIT-PIV)
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 December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes