EMA/108301/2024

European Medicines Agency decision

P/0086/2024

of 21 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for glucagon analogue linked to a human immunoglobulin Fc fragment (HM15136) (EMEA-003170-PIP01-21-M02) 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.

European Medicines Agency decision

P/0086/2024

of 21 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for glucagon analogue linked to a human immunoglobulin Fc fragment (HM15136) (EMEA-003170-PIP01-21-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0468/2022 issued on 18 November 2022 and the decision P/0100/2023 issued on 10 March 2023,

Having regard to the application submitted by Hanmi Pharm. Co., Ltd. on 15 November 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 February 2024, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 glucagon analogue linked to a human immunoglobulin Fc fragment (HM15136), solution for injection, subcutaneous use, 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 Hanmi Pharm. Co., Ltd., 14 Wiryeseong-daero, Songpa-gu, 05545 – Seoul, Republic of Korea.

EMA/PDCO/537971/2023
Amsterdam, 23 February 2024

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

EMEA-003170-PIP01-21-M02

Scope of the application

Active substance(s):

Glucagon analogue linked to a human immunoglobulin Fc fragment (HM15136)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of congenital hyperinsulinism

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Hanmi Pharm. Co., Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Hanmi Pharm. Co., Ltd. submitted to the European Medicines Agency on 15 November 2023 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0468/2022 issued on 18 November 2022 and the decision P/0100/2023 issued on 10 March 2023.

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

The procedure started on 3 January 2024.

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 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 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 congenital hyperinsulinism

2.1.1. Indication(s) targeted by the PIP

Treatment of congenital hyperinsulinism (CHI)

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)

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Generation of comparability data between pre-filled syringe and sterile vial and insulin syringe. **Study 2** Evaluation of the validity of syringe performance through dosing accuracy and precision testing.
Non-clinical studies	**Study 3 (2019-0556)** Definitive juvenile rat toxicity study
Clinical studies	**Study 4 (HM-GCG-201)** Open-label multiple dose trial to evaluate pharmacokinetics, safety, and activity of HM15136 as add-on to best standard of care in children from 2 years to less than 18 years of age (and adults) with congenital hyperinsulinism with persistent hypoglycaemia. **Study 5 (HM-GCG-301)** Double-blind, randomised, placebo controlled trial to evaluate pharmacokinetics, safety, and efficacy of HM15136 as add-on to best standard of care in children from 1 month to less than 12 years of age with congenital hyperinsulinism with persistent hypoglycaemia.

	Study 6 (HM-GCG-302) Double-blind, randomised, placebo controlled trial to evaluate pharmacokinetics, safety, and efficacy of HM15136 as add-on to best standard of care in children from birth to less than 1 year of age with congenital hyperinsulinism requiring continuous intravenous glucose administration to prevent/manage hypoglycaemia.
Modelling and simulation studies	**Study 7** Modelling and simulation study to evaluate the use of HM15136 in children from birth to less than 18 years of age with congenital hyperinsulinism with persistent hypoglycaemia.
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 June 2029
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.