EMA/501874/2008

European Medicines Agency decision

P/0468/2022

of 18 November 2022

on the agreement of a paediatric investigation plan for glucagon analogue linked to a human immunoglobulin Fc fragment (HM15136) (EMEA-003170-PIP01-21) 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 Hanmi Pharm. Co., Ltd. on 20 December 2021 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 October 2022, in accordance with Article 17 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for glucagon analogue linked to a human immunoglobulin Fc fragment (HM15136), solution for injection, subcutaneous 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

This decision is addressed to Hanmi Pharm. Co., Ltd., 14 Wiryeseong-daero, Songpa-gu, 05545 – Seoul, Republic of Korea.

EMA/PDCO/632430/2022 Corr
Amsterdam, 14 October 2022

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

EMEA-003170-PIP01-21

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 16(1) of Regulation (EC) No 1901/2006 as amended, Hanmi Pharm. Co., Ltd. submitted for agreement to the European Medicines Agency on 20 December 2021 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 31 January 2022.

Supplementary information was provided by the applicant on 4 July 2022. The applicant proposed modifications to the paediatric investigation plan.

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.

   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 congenital hyperinsulinism (CHI)

2.1.1. Indication(s) targeted by the PIP

Treatment of congenital hyperinsulinism

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 2027
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