MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan

MHRA-100882-PIP01-23

Scope of the Application

Active Substance(s)

Glucagon analogue linked to a human immunoglobulin Fc fragment

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 the Decision

Pursuant to the Human Medicines Regulations 2012, Hanmi Pharm. Co., Ltd. submitted to the licensing authority on 24/04/2023 16:38 BST an application for a Paediatric Investigation Plan

The procedure started on 26/09/2023 08:29 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100882-PIP01-23

Of 20/10/2023 14:42 BST

On the adopted decision for Glucagon analogue linked to a human immunoglobulin Fc fragment (MHRA-100882-PIP01-23) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Glucagon analogue linked to a human immunoglobulin Fc fragment, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Hanmi Pharm. Co., Ltd., 14 Wiryeseong-daero, Songpa-gu, , Seoul, SOUTH KOREA, 05545

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of congenital hyperinsulinism

2.2 Indication(s) targeted by the PIP:

Treatment of congenital hyperinsulinism

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Generation of comparability data between prefilled syringes and sterile vial and insulin syringe. Study 2 Evaluation of the validity of syringe performance through dosing accuracy and precision testing.
Non-Clinical Studies	1	Study 3 (2019-0556) Definitive juvenile rat toxicity study.
Clinical Studies	3	Study 4 (HM-GCG-201) Open label, multiple dose trial to evaluate pharmacokinetics, safety and activity of HM15136 as add-on therapy in children from 2 years to less than 18 years of age (and adults) with congenital hyperinsulinism with persistent hypoglycaemia. Study 5 (MH-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.
Extrapolation, Modeling & Simulation Studies	1	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	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/06/2028
Deferral of one or more studies contained in the paediatric investigation plan:	No