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 and grant a deferral and grant a waiver

MHRA-100996-PIP01-23

Scope of the Application

Active Substance(s)

GIPR antagonist/GLP-1R agonist- AMG 133

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Amgen Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Ltd. submitted to the licensing authority on 12/05/2023 11:47 BST an application for a

The procedure started on 26/09/2023 09:26 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 and grant a deferral and grant a waiver

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-100996-PIP01-23

Of 20/12/2024 16:39 GMT

On the adopted decision for GIPR antagonist/GLP-1R agonist- AMG 133 (MHRA-100996-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 for GIPR antagonist/GLP-1R agonist- AMG 133 , Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Amgen Ltd., 216 Cambridge Science Park, Milton Road, Cambridge, UNITED KINGDOM, CB4 0WA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of obesity The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of obesity

2.2 Indication(s) targeted by the PIP:

Weight management

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

The paediatric population 6 years 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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 1 Open-label study to evaluate the safety, tolerability, and pharmacokinetics (PK) of AMG 133 in adolescents from 12 years to less than 18 years of age with overweight or obesity. Study 2 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of AMG 133 compared to placebo in adolescents from 12 years to less than 18 years of age with obesity and overweight. Study 3 Open-label study to evaluate the safety, tolerability, and pharmacokinetics of AMG 133 in children from 6 years to less than 12 years of age with obesity. Study 4 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of AMG 133 compared to placebo in children from 6 years to less than 12 years of age with obesity.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation analyses, to evaluate the use of the product in adolescents from 12 years to less than 18 years of age with obesity or overweight. Study 6 Modelling and simulation analyses, to evaluate the use of the product in

		children from 6 years to less than 12 years of age with obesity.
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:	31/12/2038
Deferral of one or more studies contained in the paediatric investigation plan:	Yes