MHRA
10 South Colonnade
Canary Wharf
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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-102466-PIP01-26

Scope of the Application

Active Substance(s)

Aleniglipron

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Tablet; Age appropriate oral formulation (mini tablet)

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

GASHERBRUM BIO, INC.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GASHERBRUM BIO, INC. submitted to the licensing authority on 18/06/2026 13:35 BST an application for a Paediatric Investigation Plan

The procedure started on 01/07/2026 07:37 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-102466-PIP01-26

Of 07/10/2026 18:20 BST

On the adopted decision for Aleniglipron (MHRA-102466-PIP01-26) 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 Aleniglipron, Tablet; Age appropriate oral formulation (mini tablet) , Oral use .

This decision is addressed to GASHERBRUM BIO, INC., 601 GATEWAY BOULEVARD, SUITE 900, SOUTH SAN FRANCISCO, UNITED STATES OF AMERICA, 94080

ANNEX I

1. Waiver

1.1 Condition:

The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Tablet Age-appropriate oral formulation (mini tablet) Route(s) of administration: Oral 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:

To reduce excess body weight and maintain weight reduction long term in children from 6 years of age and adolescents with obesity or children from 6 years of age and adolescents with overweight in the presence of at least 1 weight-related comorbid condition.

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

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet Age-appropriate formulation (mini tablet)

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral formulation.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of aleniglipron L-arginine as an adjunct to lifestyle intervention in adolescents from 12 years to less than 18 years of age with obesity or overweight with associated comorbidities. Study 3 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics and pharmacodynamics, safety and tolerability of aleniglipron L-arginine during short-term treatment 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 aleniglipron L-arginine as an adjunct to lifestyle intervention 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 support dose selection in adolescents from 12 years to less than 18 years of age with obesity or overweight with associated comorbidities. Study 6 Modelling and simulation analyses, to support

		dose selection 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:	30/09/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes