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-102458-PIP01-26

Scope of the Application

Active Substance(s)

Povetacicept (ALPN-303)

Condition(s)

Treatment of primary IgA nephropathy

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Vertex Pharmaceuticals (Europe) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Vertex Pharmaceuticals (Europe) Limited submitted to the licensing authority on 22/04/2026 12:45 BST an application for a Paediatric Investigation Plan

The procedure started on 21/05/2026 12:09 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-102458-PIP01-26

Of 25/06/2026 09:17 BST

On the adopted decision for Povetacicept (ALPN-303) (MHRA-102458-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:

agree a paediatric investigation plan and grant a deferral and grant a waiver

This decision applies to a Paediatric Investigation Plan for Povetacicept (ALPN-303), Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Vertex Pharmaceuticals (Europe) Limited , 2 Kingdom Street, Paddington, UNITED KINGDOM, W2 6BD

ANNEX I

1. Waiver

1.1 Condition:

Treatment of primary immunoglobulin A nephropathy The waiver applies to: • the paediatric population from birth to less than 2 years of age; • solution for injection, subcutaneous use; • on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of primary immunoglobulin A nephropathy

2.2 Indication(s) targeted by the PIP:

Treatment of primary immunoglobulin A nephropathy

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

From 2 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	1	Study 1 Development of a lower volume container to ensure dosing accuracy and avoid wastage
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 2 Single-arm, open-label study to evaluate safety and pharmacokinetics of povetacicept in children from 2 years to less than 18 years of age with immunoglobulin A nephropathy (IgAN).
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation analyses to evaluate the use of povetacicept in the treatment of primary IgAN in children from 2 years to less than 18 years of age. Exrapolation plan Studies 2 and 3 are part of an extrapolation plan covering the paediatric population from 2 years to less than 18 years of age, as agreed by the Regulatory Agency
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:	31/03/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes