

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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-102213-PIP01-25

Scope of the Application

Active Substance(s)

Ianalumab

Condition(s)

Treatment of Systemic Lupus Erythematosus

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Novartis Pharmaceuticals UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novartis Pharmaceuticals UK Limited submitted to the licensing authority on 19/03/2026 09:57 GMT an application for a Paediatric Investigation Plan

The procedure started on 17/04/2026 12:50 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-102213-PIP01-25

Of 27/08/2026 11:48 BST

On the adopted decision for Ianalumab (MHRA-102213-PIP01-25) 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 Ianalumab, Solution for injection , Subcutaneous use .

This decision is addressed to Novartis Pharmaceuticals UK Limited, 2nd Floor WestWorks Building, White City Place, 195 Wood lane, London, UNITED KINGDOM, W12 7FQ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of systemic lupus erythematosus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of systemic lupus erythematosus

2.2 Indication(s) targeted by the PIP:

Treatment of active lupus nephritis

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

The paediatric population from 5 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	2	Study 1 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics (PK), pharmacodynamic (PD), efficacy and safety of ianalumab as add-on to standard of care in adolescents from 12 years to less than 18 years of age with active lupus nephritis. Study 2 Open-label, uncontrolled trial to evaluate PK, PD, efficacy and safety of ianalumab as add-on to standard of care in children and adolescents from 5 years to less than 18 years of age with active lupus nephritis.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to support dose selection of ianalumab for paediatric patients from 5 years to less than 18 years of age with active lupus nephritis. Study 4 Extrapolation study to support efficacy and safety assumptions in the paediatric population based on extrapolation from adults with active lupus nephritis and from children with other indications treated with ianalumab.
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:	Yes
Date of completion of the paediatric investigation plan:	30/09/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes