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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (EMEA-002559-PIP03-19) and to the deferral

MHRA-102415-PIP01-26-M01

Scope of the Application

Active Substance(s)

Nipocalimab

Condition(s)

Treatment of autoimmune haemolytic anaemia

Pharmaceutical Form(s)

Solution for infusion Concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 17/03/2026 18:52 GMT an application for a Modification

The procedure started on 30/03/2026 09:43 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-102415-PIP01-26-M01

Of 03/07/2026 08:09 BST

On the adopted decision for Nipocalimab (MHRA-102415-PIP01-26-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Nipocalimab, Solution for infusion Concentrate for solution for infusion , Intravenous use .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way Buckinghamshire, High Wycombe, UNITED KINGDOM, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of autoimmune haemolytic anaemia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for infusion Concentrate for solution for infusion Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of autoimmune haemolytic anaemia

2.2 Indication(s) targeted by the PIP:

Treatment of warm autoimmune haemolytic anaemia (wAIHA)

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for infusion Concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	2	Study 1 Modelling and simulation study to support the use of nipocalimab for the treatment of autoimmune haemolytic anaemia in children and adolescents from 2 years to less than 18 years of age. Study 2 Extrapolation study to support the use of nipocalimab for the treatment of autoimmune haemolytic anaemia in children and adolescents from 2 years to less than 18 years of age.
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:	31/03/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes