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-100301-PIP05-23

Scope of the Application

Active Substance(s)

Nipocalimab

Condition(s)

Treatment of Idiopathic inflammatory myopathies

Pharmaceutical Form(s)

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 27/09/2023 15:51 BST an application for a

The procedure started on 15/01/2024 17:24 GMT

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-100301-PIP05-23

Of 23/02/2024 16:01 GMT

On the adopted decision for Nipocalimab (MHRA-100301-PIP05-23) 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 Nipocalimab , Concentrate for solution for infusion , INTRAVENOUS .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of idiopathic inflammatory myopathies (IIM) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): 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 Idiopathic inflammatory myopathies (IIM)

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile dermatomyositis, treatment of immune mediated necrotizing myopathy and treatment of anti-synthetase syndrome.

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):

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, pharmacokinetic (PK)/ receptor occupancy / pharmacodynamic (PD) study, to evaluate the use of the product in children and adolescents from 2 years to less than 18 years of age with juvenile dermatomyositis (JDM). Extrapolation Plan Study 1 is part of the extrapolation plan of efficacy data from adults with idiopathic inflammatory myopathies (IIM) and generalised myasthenia gravis (gMG), and adolescents and paediatric patients with generalised myasthenia gravis (gMG) to the paediatric population from 2 years to less than 18 years of age with juvenile dermatomyositis, immune-mediated necrotising myopathy and treatment of anti-synthetase syndrome, 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:	31/05/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes