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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-100301-PIP01-21

Scope of the Application

Active Substance(s)

Anti-neonatal Fc receptor human monoclonal antibody(Nipocalimab)

Condition(s)

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Pharmaceutical Form(s)

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 29/11/2021 14:04 GMT an application for a

The procedure started on 07/03/2022 13:24 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 grant a product specific 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-PIP01-21

Of 28/03/2022 17:06 BST

On the adopted decision for Anti-neonatal Fc receptor human monoclonal antibody(Nipocalimab) (MHRA-100301-PIP01-21) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a for Anti-neonatal Fc receptor human monoclonal antibody(Nipocalimab), Solution for infusion , Intravenous use .

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:

1.1 Condition: Treatment of chronic inflammatory demyelinating polyradiculoneuropathy The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age Pharmaceutical form(s): 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 for the paediatric population from birth to less than 2 years of age; on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible for the paediatric population from 2 years to less than 18 years of age.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not Applicable

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	