MHRA
10 South Colonnade
Canary Wharf
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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-100628-PIP01-22

Scope of the Application

Active Substance(s)

Sibeprenlimab

Condition(s)

Treatment of primary immunoglobulin A nephropathy

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Otsuka Pharmaceutical Netherlands B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Otsuka Pharmaceutical Netherlands B.V. submitted to the licensing authority on 27/07/2022 11:19 BST an application for a Paediatric Investigation Plan

The procedure started on 16/01/2023 08:39 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-100628-PIP01-22

Of 13/02/2023 16:47 GMT

On the adopted decision for Sibeprenlimab (MHRA-100628-PIP01-22) 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 Sibeprenlimab, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Otsuka Pharmaceutical Netherlands B.V., Herikerbergweg 292, CT Amsterdam, NETHERLANDS, 1101

ANNEX I

1. Waiver

1.1 Condition:

Treatment of primary immunoglobulin A nephropathy 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 injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: 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:

The paediatric population 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	0	Not applicable.
Non-Clinical Studies	1	Study 1 An enhanced prenatal and postnatal development (ePPND) study in cynomolgus monkeys.
Clinical Studies	1	Study 2 (Trial 417-201-00009) Open-label, repeat-dose trial to evaluate the pharmacokinetics (PK), pharmacodynamics (PD), safety, and tolerability of sibeprenlimab administered subcutaneously (SC) in paediatric subjects 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 study to evaluate the use of sibeprenlimab in paediatric subjects from 2 years to less than 18 years of age with immunoglobulin A nephropathy.
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:	30/04/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes