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

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver.

MHRA-100832-PIP01-23-M01

Scope of the Application

Active Substance(s)

LANADELUMAB

Condition(s)

Prevention of attacks of idiopathic non-histaminergic angioedema (INHA).

Pharmaceutical Form(s)

Solution for injection.

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Takeda Pharmaceuticals International AG Ireland Branch

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Takeda Pharmaceuticals International AG Ireland Branch submitted to the licensing authority on 05/01/2023 11:33 GMT an application for a Modification

The procedure started on 17/05/2023 14:54 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 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-100832-PIP01-23-M01

Of 05/06/2023 10:46 BST

On the adopted decision for LANADELUMAB (MHRA-100832-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

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

Refusal to agree a modification of a paediatric investigation plan and granting a waiver in all age groups for the listed condition(s).

This decision applies to a Modification for LANADELUMAB, Solution for injection. , SUBCUTANEOUS USE. .

This decision is addressed to Takeda Pharmaceuticals International AG Ireland Branch, Block 2 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin, IRELAND, D02 HW68

ANNEX I

1. Waiver

1.1 Condition:

Prevention of attacks of idiopathic non-histaminergic angioedema (INHA). 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 injection. Route(s) of administration: SUBCUTANEOUS USE. Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Studies 1, 2, 3 and 4 were deleted during procedure MHRA-100832-PIP01-23-M01.

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	0	Not Applicable.
Non-Clinical Studies	0	Not Applicable.
Clinical Studies	0	Not Applicable.
Extrapolation, Modeling & Simulation Studies	0	Not Applicable.
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	