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-100476-PIP01-22

Scope of the Application

Active Substance(s)

Anti-(alpha-synuclein) human monoclonal antibody

Condition(s)

Treatment of Multiple System Atrophy, Treatment of Parkinson's Disease

Pharmaceutical Form(s)

Solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

H. Lundbeck A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, H. Lundbeck A/S submitted to the licensing authority on 15/03/2022 15:37 GMT an application for a Waiver

The procedure started on 31/08/2022 08:57 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-100476-PIP01-22

Of 11/10/2022 17:09 BST

On the adopted decision for Anti-(alpha-synuclein) human monoclonal antibody (MHRA-100476-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:

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

This decision applies to a Waiver for Anti-(alpha-synuclein) human monoclonal antibody, Solution for infusion , INTRAVENOUS USE .

This decision is addressed to H. Lundbeck A/S, Ottiliavej 9, Valby, DENMARK, 2500

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Multiple System Atrophy The waiver applies / applied to: Paediatric Subset(s): All subsets of 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 disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). Reason for Refusing Waiver: Not Applicable 1.Waiver 1.2 Condition: Treatment of Parkinson's Disease The waiver applies / applied to: Paediatric Subset(s): All subsets of 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 ineffective.

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:	