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-101106-PIP01-23

Scope of the Application

Active Substance(s)

LY3884963 (PR006A)

Condition(s)

Treatment of Frontotemporal Dementia

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

All routes of administration

Name / Corporate name of the PIP applicant

Prevail Therapeutics Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Prevail Therapeutics Inc. submitted to the licensing authority on 16/08/2023 16:52 BST an application for a Paediatric Investigation Plan

The procedure started on 03/12/2023 11:06 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-101106-PIP01-23

Of 30/12/2024 14:16 GMT

On the adopted decision for LY3884963 (PR006A) (MHRA-101106-PIP01-23) 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 Paediatric Investigation Plan for LY3884963 (PR006A), All pharmaceutical forms , INTRACISTERNAL .

This decision is addressed to Prevail Therapeutics Inc., 430 E 29th Street, Suite 1520, New York, UNITED STATES OF AMERICA, 10016

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Frontotemporal Dementia

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