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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100230-PIP01-21)

MHRA-100230-PIP01-21-M01

Scope of the Application

Active Substance(s)

Nerandomilast

Condition(s)

Treatment of fibrosing interstitial lung disease

Pharmaceutical Form(s)

Film-coated tablet, Age-appropriate oral dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Boehringer Ingelheim International GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Boehringer Ingelheim International GmbH submitted to the licensing authority on 17/04/2025 12:32 BST an application for a Modification

The procedure started on 06/05/2025 08:12 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 accept change(s) to the agreed paediatric investigation plan

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-100230-PIP01-21-M01

Of 25/07/2025 17:14 BST

On the adopted decision for Nerandomilast (MHRA-100230-PIP01-21-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Nerandomilast, Film-coated tablet, Age-appropriate oral dosage form , ORAL USE .

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, Ingelheim am Rhein, GERMANY, 55216

ANNEX I

1. Waiver

1.1 Condition:

Treatment of fibrosing interstitial lung disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Film-coated tablet Age appropriate oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of fibrosing interstitial lung disease

2.2 Indication(s) targeted by the PIP:

Treatment of fibrosing interstitial lung disease in paediatric patients from 2 years to less than 18 years of age

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):

Film-coated tablet Age appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid dosage form.
Non-Clinical Studies	2	Study 2 Dose range-finding juvenile-rat toxicity study. Study 3 Definitive juvenile-rat toxicity study.
Clinical Studies	1	Study 4 (1305.0022) Double-blind placebo controlled 6 month study to evaluate the clinical activity, the dose-exposure and safety of nerandomilast (Part A) in children and adolescents from 2 years to less than 18 years of age with fibrosing interstitial lung disease, followed by an open label phase with active treatment (Part B).
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation study to determine the dose of nerandomilast in children and adolescents with fibrosing interstitial lung disease. Study 6 Extrapolation study to evaluate the use of nerandomilast in children and adolescents with fibrosing interstitial lung disease.
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:	Yes
Date of completion of the paediatric investigation plan:	30/09/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes