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 and to the deferral

MHRA-100229-PIP01-21-M01

Scope of the Application

Active Substance(s)

NINTEDANIB

Condition(s)

Treatment of fibrosing Interstitial Lung Diseases (ILD)

Pharmaceutical Form(s)

Capsule, soft

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 10/11/2021 14:06 GMT an application for a Modification

The procedure started on 15/02/2022 17:51 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100229-PIP01-21-M01

Of 24/02/2022 16:15 GMT

On the adopted decision for NINTEDANIB (MHRA-100229-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 NINTEDANIB, Capsule, soft , 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 Diseases (ILD) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Capsule, soft 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 Diseases (ILD)

2.2 Indication(s) targeted by the PIP:

Treatment of fibrosing Interstitial Lung Diseases (ILD) in paediatric patients

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, soft

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age appropriate oral solid dosage form.
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 2 (1199.337) 6-month, double-blind, placebo-controlled study to evaluate the dose-exposure and safety of nintedanib (Part A), followed by an open label phase with active treatment (Part B) in children 6 years to less than 18 years of age with fibrosing interstitial lung diseases (ILD)
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to define dose regimen in children from 6 years to less than 18 years of age with fibrosing interstitial lung diseases Study 4 Extrapolation study to summarise - synthesise all available data in adults in the various conditions and make inferences regarding efficacy and safety of nintedanib to the paediatric population
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:	31/03/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes