MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100230-PIP01-21

Scope of the Application

Active Substance(s)

Thienopyrimidine Derivative

Condition(s)

Treatment of fibrosing interstitial lung disease

Pharmaceutical Form(s)

Film-coated tablet; Age appropriate oral solid 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 25/10/2021 12:31 BST an application for a

The procedure started on 18/02/2022 10:03 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 agree a paediatric investigation plan and grant a deferral and grant a 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-100230-PIP01-21

Of 03/03/2022 09:13 GMT

On the adopted decision for Thienopyrimidine Derivative (MHRA-100230-PIP01-21) 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 a paediatric investigation plan

This decision applies to a for Thienopyrimidine Derivative , Film-coated tablet; Age appropriate oral solid 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 Double-blind placebo controlled 6 month study to evaluate the clinical activity, the dose-exposure and safety of thienopyrimidine derivative (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 thienopyrimidine derivative in children and adolescents with fibrosing interstitial lung disease. Study 6 Extrapolation study to evaluate the use of thienopyrimidine derivative 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