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-101622-PIP01-24

Scope of the Application

Active Substance(s)

Derivative of azabicycloheptane-carboxamide

Condition(s)

Treatment of bronchiectasis

Pharmaceutical Form(s)

Film-coated tablet

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 24/09/2024 13:02 BST an application for a Paediatric Investigation Plan

The procedure started on 05/11/2024 08:06 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 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-101622-PIP01-24

Of 21/01/2025 13:41 GMT

On the adopted decision for Derivative of azabicycloheptane-carboxamide (MHRA-101622-PIP01-24) 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 Paediatric Investigation Plan for Derivative of azabicycloheptane-carboxamide, Film-coated tablet , 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 bronchiectasis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Film-coated tablet Route(s) of administration: ORAL 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).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of bronchiectasis

2.2 Indication(s) targeted by the PIP:

Treatment of bronchiectasis

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

The paediatric population from 1 year to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of lower strength (2 mm tablets) appropriate to the paediatric population from 1 year to less than 18 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 (1397-0019) Double-blind, randomised, placebo controlled trial to evaluate safety and efficacy of derivative of azabicycloheptane-carboxamide (BI 1291583) in children from 6 years to less than 18 years of age with bronchiectasis confirmed by high resolution computed tomography scan with a risk of future exacerbations (history of pulmonary exacerbations and clinical symptoms). Study 3 (1397-0030) Single arm uncontrolled trial to evaluate safety and pharmacokinetics of BI 1291583 in children from 1 year to less than 6 years of age with bronchiectasis confirmed by high resolution computed tomography scan with a risk of future exacerbations (history of pulmonary exacerbations and clinical symptoms).
Extrapolation, Modeling & Simulation Studies	2	Study 4 Modelling and simulation analyses (PopPK) to predict age-group staggered initial paediatric doses to be used in further clinical studies, and to confirm or modify the paediatric posology compared

		to the regimen used in clinical trials. Extrapolation Plan Studies 1397-0012, 1397-0013, 1397-0014, 1397-0019 and 1397-0030 are part of the extrapolation plan of efficacy data from adult patients to the paediatric population from 1 year to less than 18 years of age with condition bronchiectasis.
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:	No
Date of completion of the paediatric investigation plan:	31/12/2033
Deferral of one or more studies contained in the paediatric investigation plan:	Yes