EMADOC-1700519818-2107010

European Medicines Agency decision

EMA/PE/0000238807

of 16 May 2025

on the acceptance of a modification of an agreed paediatric investigation plan for derivative of azabicycloheptane-carboxamide (BI 1291583) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0252/2024 issued on 19 July 2024,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 18 December 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 March 2025, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for derivative of azabicycloheptane-carboxamide (BI 1291583), including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 - Ingelheim Am Rhein, Germany.

EMADOC-1700519818-1849504 Corr[1]
Amsterdam, 28 March 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000238807

Scope of the application

Active substance(s):

Derivative of azabicycloheptane-carboxamide (BI 1291583)

Invented name and authorisation status:

See Annex II

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 opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 18 December 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0252/2024 issued on 19 July 2024.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

[1] 8 May 2025.

The procedure started on 27 January 2025.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of bronchiectasis

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- film-coated tablet, oral route;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

2. Paediatric investigation plan

2.1. Condition:

Treatment of bronchiectasis

2.1.1. Indication(s) targeted by the PIP

Treatment of bronchiectasis

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year of age to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Measures

Area	Description
Quality-related studies	**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	Not applicable
Clinical studies	**Study 2 (1397-0019)** Double-blind, randomised, placebo-controlled trial to evaluate safety, efficacy and pharmacokinetics of derivative of azabicycloheptane-carboxamide (BI 1291583) in children from 6 years to less than 12 years of age and children from 12 years to less than 18 years of age weighing less than 35kg 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 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). **Study 5 (1394-0014)** *This study was added during procedure EMA/PE/0000238807* Multi-centre, double-blind, randomised, placebo-controlled trial to investigate the efficacy, safety, and tolerability of BI 1291583 at a dose of 2.5 mg in children from 12 years to less than 18 years of age weighing at least 35kg (and in adults) with bronchiectasis confirmed by high resolution computed tomography scan with a risk of future exacerbations (history of pulmonary exacerbations and clinical symptoms).
Modelling and simulation analyses	**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.
Other studies	Not applicable
Extrapolation plan	Studies 1397-0012, 1397-0013, 1397-0014 (PIP study 5), 1397-0019 (PIP study 2) and 1397-0030 (PIP study 3) are part of the extrapolation plan of efficacy data from adult patients and adolescent patients to the paediatric population from 1 year to less than 18 years of age with condition bronchiectasis.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.