EMA/296571/2024

European Medicines Agency decision

P/0252/2024

of 19 July 2024

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for derivative of azabicycloheptane-carboxamide (EMEA-003451-PIP01-23) 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 application submitted by Boehringer Ingelheim International GmbH on 26 May 2023 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 May 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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

A paediatric investigation plan for derivative of azabicycloheptane-carboxamide, film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for derivative of azabicycloheptane-carboxamide, film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for derivative of azabicycloheptane-carboxamide, film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

EMA/PDCO/94312/2024
Amsterdam, 31 May 2024

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-003451-PIP01-23

Scope of the application

Active substance(s):

Derivative of azabicycloheptane-carboxamide

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 16(1) of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted for agreement to the European Medicines Agency on 26 May 2023 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 10 July 2023.

Supplementary information was provided by the applicant on 23 February 2024.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

2. The measures and timelines of the agreed 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 and efficacy of derivative of azabicycloheptane-carboxamide in children from 6 years of age 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 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).
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, 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.

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 December 2033
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.