EMA/494437/2023

European Medicines Agency decision

P/0454/2023

of 9 November 2023

on the acceptance of a modification of an agreed paediatric investigation plan for abrocitinib (Cibinqo), (EMEA-002312-PIP01-17-M02) 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/0391/2018 issued on 7 December 2018 and the decision P/0023/2020 issued on 3 January 2020,

Having regard to the application submitted by Pfizer Europe MA EEIG on 3 July 2023 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 13 October 2023, 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.

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

[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 abrocitinib (Cibinqo), tablet, age-appropriate oral liquid dosage form, oral use, 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 Pfizer Europe MA EEIG, 17 Boulevard de la Plaine, 1050 – Brussels, Belgium.

EMA/PDCO/321382/2023
Amsterdam, 13 October 2023

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

EMEA-002312-PIP01-17-M02

Scope of the application

Active substance(s):

Abrocitinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Tablet

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 3 July 2023 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/0391/2018 issued on 7 December 2018 and the decision P/0023/2020 issued on 3 January 2020.

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

The procedure started on 14 August 2023.

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 in the scope set out in the Annex I of this opinion.

   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 atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- tablet, age-appropriate oral liquid dosage form, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of atopic dermatitis

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with moderate to severe atopic dermatitis, including the relief of pruritus, who have had an inadequate response to topical therapies or for whom these treatments are not appropriate

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Age-appropriate oral liquid dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate oral liquid dosage form suitable for patients younger from 2 years of age and older
Non-clinical studies	**Study 2** 2-week dose range-finding study in juvenile rats to evaluate tolerability of abrocitinib and to inform dose selection for the definitive juvenile toxicity study

	Study 3 Definitive juvenile toxicity study in rats to evaluate body weight, femur length and weight, haematology, lymphoid organ weights (spleen, thymus), and microscopic examination (stifle joint, thymus, spleen, mesenteric lymph node, inguinal lymph node and/or gut-associated lymphoid tissue) Toxicokinetic evaluations to determine the systemic exposure of abrocitinib
Clinical studies	**Study 4** (B7451012) Double-blind, randomised, placebo-controlled, parallel group trial to evaluate efficacy and safety of abrocitinib compared to placebo in adolescents (and adults) with moderate to severe atopic dermatitis (AD) **Study 5** (B7451013) Double-blind, randomised, placebo-controlled, parallel group trial to evaluate efficacy and safety of abrocitinib compared to placebo in adolescents (and adults) with moderate to severe atopic dermatitis (AD) **Study 6** (B7451023) Double-blind, randomised, placebo-controlled, parallel group trial to evaluate efficacy and safety of abrocitinib as add-on to topical treatment compared to placebo in children from 6 to less than 12 years of age with moderate to severe AD **Study 7** (B7451030) Double-blind, randomised, placebo-controlled, parallel group trial to evaluate efficacy and safety of abrocitinib as add-on to topical treatment in a staggered approach compared to placebo in children from 2 to less than 6 years of age with moderate to severe AD **Study 8** (B7451031) Open-label, uncontrolled trial to evaluate long-term safety of PF 04965842 in children from 2 to less than 12 years of age who participated in Studies 6 and 7
Extrapolation, modelling and simulation studies	**Study 9** Population PK analysis and exposure-response modelling of efficacy measures in adult and adolescent patients with moderate to severe AD **Study 10** Population PK analysis in paediatric patients with moderate to severe AD **Study 11** Extrapolation of PK characteristics for determining starting dose in children from 2 years to less than 12 years of age
Other studies	Not applicable.
Other measures	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2029
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:

Condition(s) and authorised indication(s)

1. Treatment of atopic dermatitis

Authorised indication(s):

- Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults who are candidates for systemic therapy
  - Invented name(s): Cibinqo
  - Authorised pharmaceutical form(s): Film-coated tablet (tablet)

    Cibinqo 50 mg film-coated tablets

    Cibinqo 100 mg film-coated tablets

    Cibinqo 200 mg film-coated tablets
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure