EMA/915818/2022

European Medicines Agency decision

P/0519/2022

of 30 December 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for obefazimod (EMEA-003196-PIP01-22) 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 Abivax on 18 February 2022 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 11 November 2022, 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 obefazimod, capsule, hard, age-appropriate oral liquid dosage form, 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 obefazimod, capsule, hard, age-appropriate oral liquid dosage form, 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 obefazimod, capsule, hard, age-appropriate oral liquid dosage form, 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 Abivax, 5 rue de la Baume, 75008 – Paris, France.

EMA/PDCO/686675/2022
Amsterdam, 11 November 2022

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

EMEA-003196-PIP01-22

Scope of the application

Active substance(s):

Obefazimod

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ulcerative colitis

Treatment of Crohn's disease

Pharmaceutical form(s):

Capsule, hard

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Abivax

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Abivax submitted for agreement to the European Medicines Agency on 18 February 2022 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 21 March 2022.

Supplementary information was provided by the applicant on 5 August 2022. The applicant proposed modifications to the paediatric investigation plan.

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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

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 ulcerative colitis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- capsule, hard; age-appropriate oral liquid dosage form;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition:

Treatment of Crohn's disease

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- capsule, hard; age-appropriate oral liquid dosage form;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of patients diagnosed with moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD)

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

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.
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (ABX464-105)** Randomised, double-blind, placebo-controlled, multi-centre study to evaluate the efficacy and safety of obefazimod once daily for induction treatment in adolescents from 16 years to less than 18 years of age (and adults) with moderate to severely active ulcerative colitis. **Study 3 (ABX464-106)** Randomised, double-blind, placebo-controlled, multi-centre study to evaluate the efficacy and safety of obefazimod in adolescents from 16 years to less than 18 years of age (and adults) with moderate to severely active ulcerative colitis. **Study 4 (ABX464-107)** Randomised, double-blind, multi-centre, placebo-controlled study to evaluate the long-term efficacy, safety of obefazimod as a maintenance therapy in adolescents from 16 years to less than 18 years of age (and adults) with moderate to severe active ulcerative colitis. **Study 5** 2-part, open-label, multi-centre, induction and maintenance study to evaluate the safety, tolerability, PK and activity of obefazimod in paediatric patients with ulcerative colitis aged from 2 years to less than 18 years.
Modelling and simulation studies	**Study 6** Pharmacokinetic (PK) modelling and dose simulation dose finding study.
Other studies	Not applicable
Extrapolation plan	Not applicable

2.2. Condition:

Treatment of Crohn's disease

2.2.1. Indication(s) targeted by the PIP

Treatment of patients diagnosed with moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD)

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

From 2 years to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Capsule, hard

Age-appropriate oral liquid dosage form

2.2.4. Measures

Area	Description
Quality-related studies	**Study 1 (same as for condition treatment of ulcerative colitis)** Development of an age-appropriate oral liquid dosage form.
Non-clinical studies	Not applicable
Clinical studies	**Study 7 (ABX464-201)** Randomised, double-blind, placebo-controlled, multi-centre study with an induction phase followed by a maintenance phase to evaluate PK, efficacy and safety of obefazimod treatment in adolescents from 16 years to less than 18 years of age (and adults) with moderate to severely active Crohn's disease. **Study 8** 2-part, open-label, multi-centre, induction and maintenance study to evaluate the safety, tolerability, PK and activity of obefazimod in paediatric patients with Crohn's disease aged from 2 years to less than 18 years.
Modelling and simulation studies	**Study 5 (same as for condition treatment of ulcerative colitis)** Pharmacokinetic (PK) modelling and dose simulation dose finding study.
Other studies	Not applicable
Extrapolation plan	Not applicable

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 June 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:

The product is not authorised anywhere in the European Community.