



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1975045

European Medicines Agency decision

EMA/PE/0000189672

of 20 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for obehazimod 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.



European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for obehazimod in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0519/2022 issued on 30 December 2022, and the decision P/0205/2024 issued on 14 June 2024,

Having regard to the application submitted by Abivax submitted on 10 October 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 31 January 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.
- (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 obefazimod, 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 Abivax, 7 Boulevard Haussmann, 75009 - Paris, France.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1731770

Amsterdam, 31 January 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000189672

Scope of the application

Active substance(s):

Obefazimod

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ulcerative colitis

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 22 of Regulation (EC) No 1901/2006 as amended, Abivax submitted to the European Medicines Agency on 10 October 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/0519/2022 issued on 30 December 2022, and the decision P/0205/2024 issued on 14 June 2024.

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

The procedure started on 25 November 2024.



Scope of the modification

Some measures 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 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.

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)

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.

	<p>Study 3 (ABX464-106)</p> <p>Randomised, double-blind, placebo-controlled, multi-centre study to evaluate the efficacy and safety of obehazimod in adolescents from 16 years to less than 18 years of age (and adults) with moderate to severely active ulcerative colitis.</p> <p>Study 4 (ABX464-107)</p> <p>Randomised, double-blind, multi-centre, placebo-controlled study to evaluate the long-term efficacy, safety of obehazimod 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.</p> <p>Study 5 (ABX464-110)</p> <p>2-part, multi-centre, double-blind induction and maintenance study to evaluate the efficacy, safety, tolerability and PK of obehazimod in paediatric patients with moderately to severely active ulcerative colitis aged from 2 years to less than 18 years.</p>
Modelling and simulation studies	<p>Study 6</p> <p>Pharmacokinetic (PK) modelling and dose simulation dose finding study.</p>
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.