



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2327416

European Medicines Agency decision

EMA/PE/0000232853

of 10 September 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for *nitrosomonas eutropha*, strain D23, live 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 726/2004¹,

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 application submitted by Aobiome Therapeutics Corp. on 16 October 2024 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 25 July 2025, 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 nitrosomonas eutropha, strain D23, live, 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 nitrosomonas eutropha, strain D23, live, 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 nitrosomonas eutropha, strain D23, live, 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 Aobiome Therapeutics Corp., 160 Alewife Brook Parkway # 1008, Cambridge - MA 02138-1102, United States.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2112663

Amsterdam, 25 July 2025

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

EMA/PE/0000232853

Scope of the application

Active substance(s):

Nitrosomonas eutropha, strain D23, live

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Cutaneous spray

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Aobiome Therapeutics Corp.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Aobiome Therapeutics Corp. submitted for agreement to the European Medicines Agency on 16 October 2024 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 25 November 2024.

Supplementary information was provided by the applicant on 22 April 2025. 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 atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 1 month of age;
- cutaneous spray, cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of atopic dermatitis

2.1.1. Indication(s) targeted by the PIP

Treatment of mild to moderate atopic dermatitis (AD)

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

From 1 month to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cutaneous spray

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (PRB244-02) Double-blind, randomised, placebo-controlled trial to evaluate safety, efficacy and tolerability of <i>Nitrosomonas eutropha</i>, strain D23, live in adolescents from 12 years to less than 18 years of age (and adults) with mild to moderate atopic dermatitis. Study 2 (PRB244- 03) Double-blind, randomised, placebo- controlled trial to evaluate safety, efficacy and tolerability of <i>Nitrosomonas eutropha</i>, strain D23, live in adolescents from 12 years to less than 18 years of age (and adults) with mild to moderate atopic dermatitis.

	Study 3 (PRB244-04) Open-label, uncontrolled extension study to evaluate long-term safety of <i>Nitrosomonas eutropha</i>, strain D23, live in adolescents from 12 years to less than 18 years of age (and adults) with mild to moderate atopic dermatitis. Study 4 (Maximal Use Trial (MUsT)) Open-label trial to evaluate pharmacokinetics, safety, and tolerability of <i>Nitrosomonas eutropha</i>, strain D23, live in children from 1 month to less than 18 years of age (and adults) with mild to moderate atopic dermatitis. Study 5 Double-blind, randomised, placebo-controlled trial to evaluate safety, efficacy and tolerability of <i>Nitrosomonas eutropha</i>, strain D23, live in children from 1 month to less than 12 years of age with mild to moderate atopic dermatitis.
Modelling and simulation analyses	Not applicable
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:	Yes
Date of completion of the paediatric investigation plan:	By June 2030
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.