EMADOC-1700519818-1840316

European Medicines Agency decision

EMA/PE/0000226657

of 28 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for abelacimab 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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on the acceptance of a modification of an agreed paediatric investigation plan for abelacimab 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 726/2004[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/0127/2022 issued on 13 April 2022,

Having regard to the application submitted by Anthos Therapeutics, Inc. on 9 September 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 13 December 2024, 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 abelacimab, 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 Anthos Therapeutics Inc., 55 Parkway Terrace Suite 103, Cambridge – 02138-3350, USA.

EMADOC-1700519818-1694106
Amsterdam, 13 December 2024

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

EMA/PE/0000226657

Scope of the application

Active substance(s):

Abelacimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of thromboembolic events

Prevention of thromboembolic events

Pharmaceutical form(s):

Concentrate for solution for injection/infusion

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Anthos Therapeutics, Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Anthos Therapeutics, Inc. submitted to the European Medicines Agency on 9 September 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0127/2022 issued on 13 April 2022.

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

The procedure started on 14 October 2024.

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 members of Liechtenstein and Norway agree 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 thromboembolic events

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- concentrate for solution for injection, intravenous use, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

1.2. Condition:

Prevention of thromboembolic events

The waiver applies to:

- the paediatric population from birth to less than 28 days of age;
- concentrate for solution for injection, intravenous use, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Prevention of thromboembolic events

2.1.1. Indication(s) targeted by the PIP

Prevention of thromboembolic events in paediatric patients with malignancies and high risk for thrombosis

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

From 28 days of age to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Concentrate for solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Compatibility study
Non-clinical studies	**Study 2** Enhanced pre and postnatal development study
Clinical studies	**Study 3** Open-label, single arm, single dose, four cohort staggered start study to evaluate pharmacokinetics (PK), pharmacodynamics (PD), safety, activity, immunogenicity and to contribute to modelling of the PK/PD of abelacimab in children from 28 days to less than 18 years of age with malignancies and high risk for thrombosis. **Study 4** Open-label, randomised, multiple dose, active controlled trial to evaluate safety, efficacy and immunogenicity of abelacimab against standard of care in children from 28 days to less than 18 years of age with malignancies and high risk for thrombosis.
Extrapolation, modelling and simulation studies	**Study 5** Modelling and simulation study to define and confirm the dose of abelacimab in children from 28 days to less than 18 years of age with malignancies and high risk for thrombosis.
Other studies	**Study 6** Ex-vivo contact surface study. **Study 7** In vitro concentration – response study.
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:	No
Date of completion of the paediatric investigation plan:	By December 2034
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.