EMADOC-1700519818-1788084

European Medicines Agency decision

EMA/PE/0000182447

of 6 December 2024

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

EMA/PE/0000182447

of 6 December 2024

on the acceptance of a modification of an agreed paediatric investigation plan for amlitelimab 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/0542/2023 issued on 21 December 2023,

Having regard to the application submitted by Sanofi Winthrop Industrie on 8 July 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 18 October 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 amlitelimab, 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 Sanofi Winthrop Industrie, 82 Avenue Raspail, 94250 Gentilly, France.

EMADOC-1700519818-1617677 Corr[1]
Amsterdam, 18 October 2024

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

EMA/PE/0000182447

Scope of the application

Active substance(s):

Amlitelimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Solution for injection in pre-filled syringe

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Sanofi Winthrop Industrie

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Winthrop Industrie submitted to the European Medicines Agency on 8 July 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/0542/2023 issued on 21 December 2023.

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

The procedure started on 19 August 2024.

[1] 13/11/2024

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 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 6 months of age;
- solution for injection in pre-filled syringe, subcutaneous 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 moderate-to-severe atopic dermatitis (AD) in patients who are candidates for systemic therapy

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

From 6 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection in pre-filled syringe

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of a lower strength of solution for injection, appropriate for the paediatric population from 6 months to less than 12 years of age
Non-clinical studies	**Study 2 (TER0761)** Reprotox: (enhanced) pre- and postnatal development study in cynomolgus monkeys
Clinical studies	**Study 3 (EFC17559, COAST 1)** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in adolescents from 12 years to

	less than 18 years of age (and adults) with moderate to severe atopic dermatitis (AD) **Study 4 (EFC17560, COAST 2)** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in adolescents from 12 years to less than 18 years of age (and adults) with moderate to severe AD **Study 5 (EFC17561, SHORE)** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in adolescents from 12 years to less than 18 years of age (and adults) with moderate to severe AD on background topical corticosteroids **Study 6 (EFC17600, ESTUARY)** Double-blind, randomised, placebo-controlled trial to evaluate treatment response and safety of amlitelimab monotherapy compared to treatment withdrawal in participants in Study 3 (EFC17559), Study 4 (EFC17560) and Study 5 (EFC17561) **Study 7 (EFC18128)** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in children from 6 months to less than 12 years of age and adolescents from 12 years to less than 18 years of age with a body weight below 40 kg with moderate to severe AD
Modelling and simulation studies	**Study 8** Population pharmacokinetic (PK) analysis to determine the PK of amlitelimab in children from 6 months to less than 12 years of age with moderate to severe AD
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 December 2032
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.