EMA/566037/2023

European Medicines Agency decision

P/0542/2023

of 21 December 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for amlitelimab (EMEA-003233-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 Sanofi Winthrop Industrie on 22 April 2023 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 15 December 2023, 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, 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 amlitelimab, solution for injection in pre-filled syringe, subcutaneous 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 amlitelimab, solution for injection in pre-filled syringe, subcutaneous 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 amlitelimab, solution for injection in pre-filled syringe, subcutaneous 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 Sanofi Winthrop Industrie, 82 Avenue Raspail, 94250 – Gentilly, France.

EMA/PDCO/525822/2023
Amsterdam, 15 December 2023

Final opinion of the Paediatric Committee on the agreement of a Paediatric Investigation plan and a deferral and a waiver

EMEA-003233-PIP01-22

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 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Winthrop Industrie submitted for agreement to the European Medicines Agency on 22 April 2023 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.

An Opinion was adopted by the Paediatric Committee on 13 October 2023 for the above mentioned product. Sanofi Winthrop Industrie received the Paediatric Committee Opinion on 23 October 2023.

On 16 November 2023 Sanofi Winthrop Industrie submitted to the European Medicines Agency a written request, including detailed grounds for re-examination of the Opinion.

The re-examination procedure started on 17 November 2023.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   1.1. to revise its opinion and

   - 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 Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   1.2. following re-examination, to amend the measures of the paediatric investigation plan.

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 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)** 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) 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)** 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)** Double-blind, randomised, placebo-controlled trial to evaluate maintenance of treatment response to amlitelimab 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 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.