EMADOC-1700519818-2039163

European Medicines Agency decision

EMA/PE/0000236669

of 14 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for ritlecitinib (Litfulo) 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 ritlecitinib (Litfulo) 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/0289/2023 issued on 4 August 2023,

Having regard to the application submitted by Pfizer Europe MA EEIG on 22 November 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 28 February 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan including changes to the deferral.

[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 ritlecitinib (Litfulo), including changes to the deferral, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0147/2021 issued on 14 April 2021, including subsequent modifications thereof.

Article 3

This decision is addressed to Pfizer Europe MA EEIG, Boulevard De La Plaine 17, 1050- Brussels, Belgium.

EMADOC-1700519818-1802305
Amsterdam, 28 February 2025

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

EMA/PE/0000236669

Scope of the application

Active substance(s):

Ritlecitinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of vitiligo

Pharmaceutical form(s):

Tablet

Capsule, hard

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 22 November 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/0289/2023 issued on 4 August 2023.

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

The procedure started on 2 January 2025.

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 and to the deferral 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 vitiligo

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet, capsule, hard, age-appropriate oral solid dosage form, oral use;
- 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 vitiligo

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with nonsegmental vitiligo who are candidates for systemic treatment

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Capsule, hard

Age-appropriate oral solid dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of age appropriate oral formulation suitable for children less than 12 years of age
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (B7981040)** Randomised, double-blind, 52-week placebo-controlled, multi-centre study investigating the efficacy, safety and tolerability of ritlecitinib in adolescents from 12 years to less than 18 years (and adults) with nonsegmental vitiligo

	Study 3 (B7981038) Randomized, double-blind, placebo-controlled, study to investigate the efficacy and safety of ritlecitinib in paediatric participants from 6 years to less than 18 years of age with nonsegmental vitiligo **Study 4 (B7981039)** Long-term extension study to investigate the efficacy and safety of ritlecitinib in paediatric participants 6 years to less than 18 years of age with nonsegmental vitiligo
Modelling and simulation studies	**Study 5** Population pharmacokinetic (PK) modelling and simulation analysis
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 March 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:

Condition(s) and authorised indication(s)

1. Treatment of alopecia areata

Authorised indication(s):

- Litfulo is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older
  - Invented name(s): Litfulo
  - Authorised pharmaceutical form(s): hard capsule
  - Authorised route(s) of administration: oral use
  - Authorised via the centralised procedure