EMA/553390/2023

European Medicines Agency decision

P/0026/2024

of 26 January 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ritlecitinib (Litfulo), (EMEA-002451-PIP01-18-M02) 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 European Medicines Agency's decision P/0147/2021 issued on 8 March 2021 and the decision P/0446/2022 issued on 28 October 2022,

Having regard to the application submitted by Pfizer Europe MA EEIG on 1 August 2023 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 January 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, 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 ritlecitinib (Litfulo), tablet, capsule, hard, oral use, 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 Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 - Brussels, Belgium.

EMA/PDCO/580976/2023
Amsterdam, 18 January 2024

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

EMEA-002451-PIP01-18-M02

Scope of the application

Active substance(s):

Ritlecitinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of alopecia areata

Pharmaceutical form(s):

Tablet

Capsule, hard

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 1 August 2023 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/0147/2021 issued on 8 March 2021 and the decision P/0446/2022 issued on 28 October 2022.

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

An Opinion was adopted by the Paediatric Committee on 10 November 2023 for the above mentioned product. Pfizer Europe MA EEIG received the Paediatric Committee Opinion on 20 November 2023.

On 19 December 2023 Pfizer Europe MA EEIG submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 20 December 2023.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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 to the changes regarding the measures of the paediatric investigation plan in the scope set out in the Annex I of this opinion;

1.2. following re-examination, to amend the scope of the modifications 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 alopecia areata

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet, capsule, hard, oral 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 alopecia areata

2.1.1. Indication(s) targeted by the PIP

Treatment of severe alopecia areata (including alopecia universalis and alopecia totalis)

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

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of hard capsules for children less than 12 years of age
Non-clinical studies	**Study 2 (00655269)** Definitive juvenile toxicity study in rats with a 2-month recovery phase.
Clinical studies	**Study 3 (B7981031)** Open label, non-randomized, multiple once daily dose, PK/PD study in children 6 years to less than 12 years with severe alopecia areata **Study 4 (B7981027)** Randomized, double-blind, 24-week, placebo-controlled study to evaluate the safety and efficacy of ritlecitinib in children 6 years to less than 12 years of age with severe alopecia areata

	Study 5 (B798128) Long-term, extension study to evaluate the long-term safety and long-term efficacy of ritlecitinib in participants with severe alopecia areata (AA) who successfully completed studies B7981031 or B7981027
Extrapolation, modelling and simulation studies	**Study 6** Population PK analysis to characterize the PK of ritlecitinib in adult and adolescent AA participants and for dose-prediction in children 6 years to less than 12 years of age. **Study 7** Population PK analysis to characterize the PK of ritlecitinib in adult and paediatric AA subjects and evaluate overall dosing recommendation in the paediatric AA population. **Study 8** Longitudinal exposure-response analysis of absolute SALT (severity of alopecia tool) score to characterize the temporal relationship of exposure-response of ritlecitinib on scalp hair growth in AA subjects. **Study 9** Extrapolation study to support the extrapolation of efficacy, safety and clinical PK data of ritlecitinib to adolescents with severe AA.
Other studies	Not applicable.
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:	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:

Condition(s) and authorised indication(s)

1. Treatment of alopecia areata

Authorised indication(s):

- 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 centralised procedure