

EMA/466412/2019

European Medicines Agency decision

P/0325/2019

of 11 September 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for trifarotene (CD5789) (EMA-001492-PIP02-18) 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 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by Premier Research Group Ltd on 26 October 2018 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 26 July 2019, 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 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for trifarotene (CD5789), cream, topical 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 trifarotene (CD5789), cream, topical 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 trifarotene (CD5789), cream, topical 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 Premier Research Group SLU, Camino de la Zarzuela 19-1, 28023 - Madrid, Spain.

EMA/PDCO/257598/2019
Amsterdam, 26 July 2019

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-001492-PIP02-18

Scope of the application

Active substance(s):

Trifarotene (CD5789)

Condition(s):

Treatment of ichthyoses

Pharmaceutical form(s):

Cream

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

Premier Research Group SLU

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Premier Research Ltd submitted for agreement to the European Medicines Agency on 26 October 2018 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.

The procedure started on 4 December 2018.

Supplementary information was provided by the applicant on 22 April 2019. The applicant proposed modifications to the paediatric investigation plan.

On 22 April 2019 Premier Research Ltd requested to transfer the paediatric investigation plan to Premier Research Group SLU.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

The Norwegian Paediatric Committee member 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 annex 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 ichthyoses

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- cream, topical use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition

Treatment of ichthyoses

2.1.1. Indication(s) targeted by the PIP

Treatment of Lamellar Ichthyosis

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

From 2 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of a reduced potency cream for children from 2 years to less than 12 years of age.
Non-clinical studies	1	Study 2 Definitive juvenile toxicity study in rats.
Clinical studies	3	Study 3 Randomized, multi-centre, double-blind, vehicle controlled, 12-week, safety, efficacy, and systemic exposure study followed by a 12-week open-label extension in adolescents from 12 years to less than 18 years (and adults) with moderate to severe lamellar ichthyosis.

		Study 4 Randomized, multi-centre, double-blind, vehicle controlled, safety and efficacy study in adolescents from 12 years to less than 18 years (and adults) with moderate to severe lamellar ichthyosis. Study 5 Randomized, multi-centre, double-blind, vehicle controlled, 12-week, efficacy and safety study of trifarotene cream in children from 2 years to less than 12 years, with autosomal recessive ichthyosis with lamellar scale, followed by an open-label maintenance/roll-over to study medication of 12 additional weeks.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 March 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes