EMA/568167/2021

European Medicines Agency decision

P/0442/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for fluocinolone acetonide (Iluvien 190 micrograms intravitreal implant in applicator and associated names), (EMEA-000801-PIP03-16-M01) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0156/2017 issued on 8 June 2017,

Having regard to the application submitted by Alimera Sciences Limited on 25 May 2021 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 10 September 2021, 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 and to the waiver.

(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 and to the 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

Changes to the agreed paediatric investigation plan for fluocinolone acetonide (Iluvien 190 micrograms intravitreal implant in applicator and associated names), intravitreal implant in applicator, intravitreal use, including changes to the deferral and to the waiver, 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/0091/2010 issued on 1 June 2010, including subsequent modifications thereof.

Article 3

This decision is addressed to Alimera Sciences Limited Royal Pavilion, Wellesley Road, GU11 1PZ – Aldershot, United Kingdom.

EMA/PDCO/325756/2021 Corr
Amsterdam, 10 September 2021

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

EMEA-000801-PIP03-16-M01

Scope of the application

Active substance(s):

Fluocinolone acetonide

Invented name:

Iluvien 190 micrograms intravitreal implant in applicator and associated names

Condition(s):

Treatment of non-infectious uveitis

Secondary prevention of non-infectious uveitis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Intravitreal implant in applicator

Route(s) of administration:

Intravitreal use

Name/corporate name of the PIP applicant:

Alimera Sciences Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Alimera Sciences Limited submitted to the European Medicines Agency on 25 May 2021 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/0156/2017 issued on 8 June 2017

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

The procedure started on 12 July 2021.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Amendment of the scope of the Paediatric Investigation Plan to include another condition. A waiver for a paediatric subset has been added to new condition.

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 and to the waiver in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member 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 non-infectious uveitis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- intravitreal implant in applicator, intravitreal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

1.2. Condition:

Secondary prevention of non-infectious uveitis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- intravitreal implant in applicator, intravitreal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of non-infectious uveitis

2.1.1. Indication(s) targeted by the PIP

Treatment of and prevention or relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye in children from 6 years of age

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)

Intravitreal implant in applicator

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	**Study 1** Study deleted within procedure EMEA-000801-PIP03-16-M01
Non-clinical studies	0	Not applicable

Clinical studies	1	**Study 2** Open label study to evaluate the safety and efficacy of fluocinolone intravitreal implant in children and adolescents from 6 years to less than 18 years with recurrent non-infectious uveitis affecting the posterior segment of the eye considered insufficiently responsive to, or unsuitable for, the preferred standard of care and thought to require the use of intraocular corticosteroid. (ALI-P01-21-006)
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

2.2. Condition:

Secondary prevention of non-infectious uveitis

2.2.1. Indication(s) targeted by the PIP

Treatment of and prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye in children from 6 years of age

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

From 6 years to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Intravitreal implant in applicator

2.2.4. Measures

Same as for condition treatment of chronic non-infectious uveitis

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 September 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of diabetic macular oedema

Authorised indication(s):

- ILUVIEN is indicated for the treatment of vision impairment associated with chronic diabetic macular oedema, (DMO) considered insufficiently responsive to available therapies.

2. Prevention and Treatment of non-infectious uveitis

Authorised indication(s):

- ILUVIEN is indicated for prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

Authorised pharmaceutical form(s):

Intravitreal implant in applicator

Authorised route(s) of administration:

Intravitreal use