MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral and to the waiver

MHRA-100156-PIP01-21-M01

Scope of the Application

Active Substance(s)

FLUOCINOLONE ACETONIDE

Condition(s)

Treatment of non-infectious uveitis, Secondary prevention of non-infectious uveitis

Pharmaceutical Form(s)

Intravitreal implant in applicator

Route(s) of Administration

Intravitreal use

Name / Corporate name of the PIP applicant

Alimera Sciences Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Alimera Sciences Limited submitted to the licensing authority on 25/06/2021 17:59 BST an application for a Modification

The procedure started on 17/12/2021 14:26 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan, to the deferral, and to the waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100156-PIP01-21-M01

Of 22/12/2021 16:35 GMT

On the adopted decision for FLUOCINOLONE ACETONIDE (MHRA-100156-PIP01-21-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for FLUOCINOLONE ACETONIDE, Intravitreal implant in applicator , Intravitreal use .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of non-infectious uveitis; Secondary prevention of non-infectious uveitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Intravitreal implant in applicator Route(s) of administration: Intravitreal use Reason for granting waiver (for both conditions): on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of non-infectious uveitis; Secondary prevention of non-infectious uveitis (measures are the same for both conditions)

2.2 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 the age of 6 years

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Intravitreal implant in applicator

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 Deleted in MHRA-100156-PIP01-21-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 paediatric patients from 6 years to less than 18 years of age with recurrent non-infectious uveitis affecting the posterior segment and considered insufficiently responsive to, or unsuitable for, the preferred standard of care and thought to require intraocular corticosteroid use. (ALI-P01-21-006)
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	30/09/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes