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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100089-PIP01-21-M01

Scope of the Application

Active Substance(s)

dupilumab

Condition(s)

Treatment of eosinophilic oesophagitis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

Regeneron Ireland DAC

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Regeneron Ireland DAC submitted to the licensing authority on 19/04/2021 14:41 BST an application for a Modification

The procedure started on 02/12/2021 13:29 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 and to the deferral

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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100089-PIP01-21-M01

Of 13/12/2021 14:39 GMT

On the adopted decision for dupilumab (MHRA-100089-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 dupilumab , Solution for injection , Subcutaneous use .

This decision is addressed to Regeneron Ireland DAC, One Warrington Place, Dublin, Ireland, D02 HH27

ANNEX I

1. Waiver

1.1 Condition:

Treatment of eosinophilic oesophagitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: 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(s):

Treatment of eosinophilic oesophagitis

2.2 Indication(s) targeted by the PIP:

Treatment of eosinophilic oesophagitis

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1 (R668-EE-1774) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of dupilumab as add-on to best standard of care compared to placebo in children from 12 to less than 18 years of age (and adults) with eosinophilic oesophagitis Study 2 (R668-EE-1877) Double-blind, randomised, placebo-controlled trial to evaluate PK, safety and efficacy of dupilumab as add-on to best standard of care compared to placebo in children from 2 years to less than 12 years of age with eosinophilic oesophagitis
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:	30/09/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes