**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 (MHRA-100224-PIP02-22)

MHRA-100224-PIP02-22-M01

# Scope of the Application

## Active Substance(s)

ETRASIMOD L-ARGININE

## Condition(s)

Treatment of Crohn's disease

## Pharmaceutical Form(s)

Age appropriate oral solid dosage form; Film coated tablets

## Route(s) of Administration

ORAL USE

## Name / Corporate name of the PIP applicant

Pfizer Limited

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 17/09/2024 10:01 BST an application for a Modification

The procedure started on 05/11/2024 07:52 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

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-100224-PIP02-22-M01

Of 21/01/2025 17:07 GMT

On the adopted decision for ETRASIMOD L-ARGININE (MHRA-100224-PIP02-22-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 ETRASIMOD L-ARGININE, Film-coated tablet Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM, CT139NJ

# ANNEX I

## 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of Crohn’s disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Film-coated tablet Age-appropriate oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. |

## 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of Crohn’s disease |

## 2.2 Indication(s) targeted by the PIP:

| |
|---|
| Treatment of moderately or severely active Crohn's Disease (CD). |

## 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):

| |
|---|
| Film-coated tablet Age-appropriate oral solid dosage form |

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 1 | Study 1 (PED-FORDEV) Development of an age-appropriate oral solid dosage form. |
| **Non-Clinical Studies** | 0 | Not applicable. |
| **Clinical Studies** | 1 | Study 2 (APD334 PED CD) Multicentre, 2-part, blinded doses cohort study to evaluate the efficacy, safety, and pharmacokinetics (PK), of etrasimod in children and adolescents from 2 years to less than 18 years of age with moderately to severely active Crohn's disease (CD). |
| **Extrapolation, Modeling & Simulation Studies** | 2 | Study 3 Population pharmacokinetic (PK) model to support dose selection in children and adolescents from 2 years to less than 18 years of age with moderately to severely active CD. Study 4 Population PK/ PD exposure-response model to assess and compare evaluated PD responses in adults and adolescents and children of various age and body weight groups to further support dose selection. |
| **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:** | No |

| | |
|---|---|
| **Date of completion of the paediatric investigation plan:** | 31/05/2030 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |