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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100224-PIP02-22

Scope of the Application

Active Substance(s)

Etrasimod L-arginine

Condition(s)

Treatment of Crohn’s disease

Pharmaceutical Form(s)

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

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Arena Pharmaceuticals Inc., a wholly-owned subsidiary of Pfizer Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Arena Pharmaceuticals Inc., a wholly-owned subsidiary of Pfizer Inc submitted to the licensing authority on 09/09/2022 09:53 BST an application for a Paediatric Investigation Plan

The procedure started on 14/02/2023 14:58 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 agree a paediatric investigation plan and grant a deferral and grant a 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100224-PIP02-22

Of 06/03/2023 17:50 GMT

On the adopted decision for Etrasimod L-arginine (MHRA-100224-PIP02-22) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Etrasimod L-arginine, Film-coated tablet; Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Arena Pharmaceuticals Inc., a wholly-owned subsidiary of Pfizer Inc, 66 Hudson Boulevard East, New York, UNITED STATES OF AMERICA, 10001

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