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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101540-PIP01-24

Scope of the Application

Active Substance(s)

derivative of pyrindin-2-yl)cyclopropanecarboxamide hydrochoride

Condition(s)

Treatment of psoriasis

Pharmaceutical Form(s)

Tablet, Age appropriate dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Alumis Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Alumis Inc submitted to the licensing authority on 06/08/2024 08:59 BST an application for a Paediatric Investigation Plan

The procedure started on 06/09/2024 11:18 BST

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.

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Final Decision Letter

MHRA-101540-PIP01-24

Of 20/11/2024 12:08 GMT

On the adopted decision for derivative of pyrindin-2-yl)cyclopropanecarboxamide hydrochloride (MHRA-101540-PIP01-24) 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 derivative of pyrindin-2-yl)cyclopropanecarboxamide hydrochloride, Tablet, Age appropriate dosage form , ORAL USE .

This decision is addressed to Alumis Inc, 280 East Grand Avenue, South San Francisco, CA, UNITED STATES OF AMERICA, 94080-7017

ANNEX I

1. Waiver

1.1 Condition:

Treatment of psoriasis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Tablet Age appropriate 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 psoriasis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe plaque psoriasis

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):

Tablet Age appropriate dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral formulation.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, and efficacy of ESK-001 compared to placebo in children from 12 years to less than 18 years of age with moderate to severe plaque psoriasis. Study 3 Double-blind, randomised, placebo controlled trial to evaluate pharmacokinetics, safety, and efficacy of ESK-001 compared to placebo in children from 6 years to less than 12 years of age with moderate to severe plaque psoriasis.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation analyses to evaluate the use of ESK-001 in the treatment of psoriasis in children from 6 years to less than 18 years of age.
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:	31/07/2029

Deferral of one or more studies contained in the paediatric investigation plan:	Yes