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-100304-PIP01-21

Scope of the Application

Active Substance(s)

rozibafusp alfa

Condition(s)

Treatment of systemic lupus erythematosus (SLE)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

Amgen Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Ltd. submitted to the licensing authority on 15/11/2021 10:43 GMT an application for a Paediatric Investigation Plan

The procedure started on 31/03/2022 08:47 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-100304-PIP01-21

Of 08/04/2022 15:28 BST

On the adopted decision for rozibafusp alfa (MHRA-100304-PIP01-21) 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 rozibafusp alfa, Solution for injection , Subcutaneous use .

This decision is addressed to Amgen Ltd., 216 Cambridge Science Park, Milton Road, Cambridge, United Kingdom, CB4 0WA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of systemic lupus erythematosus (SLE) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous 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 systemic lupus erythematosus (SLE)

2.2 Indication(s) targeted by the PIP:

Treatment of systemic lupus erythematosus in paediatric patients from 5 years to less than 18 years of age with an inadequate response to standard of care therapy, and who are candidates for systemic therapy.

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

The paediatric population from 5 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	1	Study 1 Double blind, randomised, placebo-controlled trial to evaluate efficacy, safety and pharmacokinetics of rozibafusp in children from 5 years to less than 8 years of age with active systemic lupus erythematosus and inadequate response to standard of care therapy.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to evaluate the use of rozibafusp in the treatment of systemic lupus erythematosus in children from 5 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:	31/03/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes