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-100421-PIP01-22

Scope of the Application

Active Substance(s)

efavaleukin 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 Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Limited submitted to the licensing authority on 18/02/2022 14:13 GMT an application for a

The procedure started on 14/11/2022 08:03 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-100421-PIP01-22

Of 05/12/2022 08:30 GMT

On the adopted decision for efavaleukin alfa (MHRA-100421-PIP01-22) 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 for efavaleukin alfa, Solution for injection , Subcutaneous use .

This decision is addressed to Amgen Limited, 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 disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of systemic lupus erythematosus (SLE)

2.2 Indication(s) targeted by the PIP:

Treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) despite receiving standard of care (SOC) 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 pharmacokinetics, safety and efficacy of efavaleukin alfa as add-on to standard of care in children from 5 years to less than 18 years of age with active SLE and inadequate response to standard of care therapy.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to establish the dose of efavaleukin alfa in children from 5 years to less than18 years of age with active SLE and inadequate response to standard of care therapy.
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:	31/03/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes