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-100776-PIP01-22-M01) and to the deferral.

MHRA-100897-PIP01-23-M01

Scope of the Application

Active Substance(s)

nemolizumab

Condition(s)

Treatment of atopic dermatitis

Pharmaceutical Form(s)

Powder for solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Galderma (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Galderma (UK) Limited submitted to the licensing authority on 20/02/2023 12:53 GMT an application for a Modification

The procedure started on 14/06/2023 14:20 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100897-PIP01-23-M01

Of 17/07/2023 09:24 BST

On the adopted decision for nemolizumab (MHRA-100897-PIP01-23-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 nemolizumab, Powder for solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Galderma (UK) Limited, Evergreen House North, Grafton Place, London Euston, London, UNITED KINGDOM, NW1 2DX

ANNEX I

1. Waiver

1.1 Condition:

Treatment of atopic dermatitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Powder for solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of atopic dermatitis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe atopic dermatitis not adequately controlled with topical treatments.

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):

Powder for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate pharmaceutical form
Non-Clinical Studies	1	Study 2 Study to evaluate the effects on pre-and postnatal development in cynomolgus monkeys and to assess the systemic exposure in dams and offspring along with milk concentrations.
Clinical Studies	7	Study 3 (SPR.118161) Placebo-controlled, randomised, multicentre, study to evaluate efficacy and safety of nemolizumab. Study 4 (SPR.118169) Placebo-controlled, randomised, multicentre, study to evaluate efficacy and safety of nemolizumab. Study 5 (SPR.118163) Single arm, open-label, long-term study to evaluate efficacy and safety of nemolizumab. Study 6 Deleted during procedure MHRA-100776-PIP01-22-M01. Study 7 Deleted during procedure MHRA-100776-PIP01-22-M01. Study 8 Deleted during procedure MHRA-100776-PIP01-22-M01. Study 9 Deleted during procedure MHRA-100776-PIP01-22-M01. Study 11 (SPR.116912) Added during procedure MHRA-100776-PIP01-22-M01. Single-arm, open-

		label study to evaluate PK, safety and activity of nemolizumab in adolescents with moderate to severe atopic dermatitis (AD). Study 12 (SPR.118126) Added during procedure MHRA-100776-PIP01-22-M01. Single-arm, open-label trial to evaluate pharmacokinetics (PK), safety and activity of nemolizumab in children from 2 years to less than 12 years with moderate to severe atopic dermatitis. Study 13 (SPR.204784) Added during procedure MHRA-100776-PIP01-22-M01. Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of nemolizumab in children from 2 years to less than 12 years with moderate to severe atopic dermatitis. Study 14 (SPR.205513) Added during procedure MHRA-100776-PIP01-22-M01. Open-label, long-term, extension trial to evaluate safety and activity of nemolizumab in children from 2 years to less than 12 years with moderate to severe atopic dermatitis.
Extrapolation, Modeling & Simulation Studies	1	Study 10 1-compartment model with 1st order absorption (PK).
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:	Yes
Date of completion of the paediatric investigation plan:	30/04/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes