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 and to the deferral

MHRA-101725-PIP01-24

Scope of the Application

Active Substance(s)

GUSELKUMAB

Condition(s)

Treatment of psoriasis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Ltd submitted to the licensing authority on 01/12/2024 21:01 GMT an application for a Paediatric Investigation Plan

The procedure started on 23/12/2024 15:07 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 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.

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Final Decision Letter

MHRA-101725-PIP01-24

Of 09/01/2025 11:19 GMT

On the adopted decision for GUSELKUMAB (MHRA-101725-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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Paediatric Investigation Plan for GUSELKUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Janssen-Cilag Ltd, 50–100 Holmers Farm Way, High Wycombe, UNITED KINGDOM, HP12 4EG

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): 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 psoriasis.

2.2 Indication(s) targeted by the PIP:

Treatment of plaque psoriasis.

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

The paediatric population from 6 years of age 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	1	Study 1 Development of an age-appropriate paediatric presentation, a single use VarioJect manual injector (pre-filled pen).
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (CNTO1959PSO3011) Active-controlled, double blind study to evaluate the PK, safety and efficacy of guselkumab in paediatric patients with plaque psoriasis.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Extrapolation to select the paediatric study dose regimen. Study 4 Extrapolation/Interpolation for exposure-response analysis.
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:	31/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes