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

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Decision Cover Letter

Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan (MHRA-100779-PIP01-22-M02) and to the deferral.

MHRA-100779-PIP01-22-M03

Scope of the Application

Active Substance(s)

GUSELKUMAB

Condition(s)

Treatment of chronic idiopathic arthritis (inc. rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis).

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 20/11/2025 13:15 GMT an application for a

The procedure started on 28/11/2025 13:06 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-100779-PIP01-22-M03

Of 18/12/2025 15:54 GMT

On the adopted decision for GUSELKUMAB (MHRA-100779-PIP01-22-M03) 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 for GUSELKUMAB, Solution for injection , SUBCUTANEOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis). 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 as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis).

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile idiopathic arthritis.

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 available.
Non-Clinical Studies	0	Not available.
Clinical Studies	1	Study 1 (CNTO1275JPA3001) Open-label trial to evaluate pharmacokinetics, safety, efficacy and immunogenicity of guselkumab in children from 5 to less than 18 years of age with active juvenile psoriatic arthritis (jPsA) despite DMARD therapy.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Modelling and simulation study to evaluate the use of guselkumab in children from 5 to less than 18 years of age with active juvenile psoriatic arthritis (jPsA) despite DMARD therapy. Study 3 Extrapolation study to evaluate the use of guselkumab in children from 5 to less than 18 years of age with active juvenile psoriatic arthritis (jPsA) despite DMARD therapy.
Other Studies	0	Not available.
Other Measures	0	Not available.

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:	30/06/2031

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