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 change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-101723-PIP01-24-M01

Scope of the Application

Active Substance(s)

USTEKINUMAB

Condition(s)

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

Pharmaceutical Form(s)

Solution for injection Concentrate for solution for infusion

Route(s) of Administration

SUBCUTANEOUS USE INTRAVENOUS 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 04/12/2024 15:48 GMT an application for a Modification

The procedure started on 14/01/2025 17:16 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-101723-PIP01-24-M01

Of 28/01/2025 10:35 GMT

On the adopted decision for USTEKINUMAB (MHRA-101723-PIP01-24-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 USTEKINUMAB, Solution for injection Concentrate for solution for infusion , INTRAVENOUS, 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 spondylarthritis 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 Concentrate for solution for infusion Route(s) of administration: SUBCUTANEOUS USE INTRAVENOUS USE Reason for granting waiver: For children from birth to less than 2 years of age, 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). For children from 2 years of age to less than 5 years of age, 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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis).

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile idiopathic arthritis (juvenile psoriatic arthritis).

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

The paediatric population from 5 years of age to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Solution for injection Concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate strength for children less than 12 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 removed during adopted procedure EMEA-000311-PIP03-11-M06. Study 3 removed during adopted procedure EMEA-000311-PIP03-11-M06. Study 4, CNTO1275JPA3001 Multicentre, open-label study to evaluate the efficacy, pharmacokinetics and safety of ustekinumab in paediatric patients from 5 years of age to less than 18 years of age with juvenile psoriatic arthritis. Added during adopted procedure EMEA-000311-PIP03-11-M06.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation study to characterize the pharmacokinetics of ustekinumab in children from 5 to less than 18 years of age with juvenile psoriatic arthritis (jPsA) and to evaluate the covariates that affect PK exposure. Added during adopted procedure

		EMEA-000311-PIP03-11-M06. Study 6 Extrapolation study to evaluate the use of ustekinumab in patients from 5 to less than 18 years of age with juvenile psoriatic arthritis. Added during adopted procedure EMEA-000311-PIP03-11-M06.
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:	30/09/2026
Deferral of one or more studies contained in the paediatric investigation plan:	YES