MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100525-PIP02-25

Scope of the Application

Active Substance(s)

TILDRAKIZUMAB

Condition(s)

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

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Almirall, S.A

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Almirall, S.A submitted to the licensing authority on 04/04/2025 17:36 BST an application for a Paediatric Investigation Plan

The procedure started on 15/05/2025 18:43 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 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.

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Final Decision Letter

MHRA-100525-PIP02-25

Of 03/02/2026 14:25 GMT

On the adopted decision for TILDRAKIZUMAB (MHRA-100525-PIP02-25) 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 Paediatric Investigation Plan for TILDRAKIZUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Almirall, S.A, Ronda General Mitre, 151, Barcelona, SPAIN, 08022

ANNEX I

1. Waiver

1.1 Condition:

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

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile psoriatic 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	1	Study 1 Development of vial dosage form based on adult formulation for dose adjustment in lower age groups for subcutaneous (SC) use.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (M-301-31) Randomised, open-label, active control trial to evaluate efficacy, pharmacokinetics and safety of tildrakizumab in paediatric subjects from 5 years to less than 18 years of age with active juvenile psoriatic arthritis despite disease-modifying antirheumatic drug (DMARD) therapy.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Population pharmacokinetics model to evaluate the use of tildrakizumab in children from 5 years to less than 18 years of age with active juvenile psoriatic arthritis (JPsA). Study 4 Extrapolation study and disease similarity report.
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