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

MHRA-100525-PIP01-22-M01

Scope of the Application

Active Substance(s)

TILDRAKIZUMAB

Condition(s)

Treatment of psoriasis

Pharmaceutical Form(s)

Solution of 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 28/04/2022 15:28 BST an application for a Modification

The procedure started on 05/05/2022 12:03 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

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-PIP01-22-M01

Of 10/05/2022 15:36 BST

On the adopted decision for TILDRAKIZUMAB (MHRA-100525-PIP01-22-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 TILDRAKIZUMAB, Solution of injection , Subcutaneous use .

This decision is addressed to Almirall, S.A., Harman House, Uxbridge, UNITED KINGDOM, UB8 1QQ

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 of 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 psoriasis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe chronic plaque psoriasis

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

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution of injection (in pre-filled syringe)

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 1 (TILD-19-12) Multicentre randomised, active-controlled clinical trial to study the efficacy, safety and pharmacokinetics of tildrakizumab in paediatric patients from 6 years to less than 18 years of age with moderate to severe psoriasis.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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