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-100625-PIP01-22-M01

Scope of the Application

Active Substance(s)

RISANKIZUMAB

Condition(s)

Treatment of psoriasis

Pharmaceutical Form(s)

Concentrate for solution for infusion; Solution for injection; Age appropriate dosage form for parenteral use

Route(s) of Administration

INTRAVENOUS USE; SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

AbbVie Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd submitted to the licensing authority on 30/03/2023 14:40 BST an application for a Modification

The procedure started on 01/08/2023 10:00 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-100625-PIP01-22-M01

Of 29/08/2023 17:00 BST

On the adopted decision for RISANKIZUMAB (MHRA-100625-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 RISANKIZUMAB, Concentrate for solution for infusion; Solution for injection; Age appropriate dosage form for parenteral use , INTRAVENOUS USE; SUBCUTANEOUS USE .

This decision is addressed to AbbVie Ltd, AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of psoriasis The waiver applies / applied to: 1. Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Age-appropriate dosage form for parenteral use 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 Subset(s): The paediatric population from birth to less than 18 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: 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 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):

Age-appropriate dosage form for parenteral use

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 (1311.PD.QUAL) Development of an age-appropriate paediatric pharmaceutical form for parenteral use.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (1311.PED) Randomised, active-controlled, evaluator blinded, trial to evaluate PK, safety and efficacy of risankizumab in patients from 6 years to less than 18 years of with moderate to severe plaque 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:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes