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-101250-PIP01-23-M01

Scope of the Application

Active Substance(s)

RISANKIZUMAB

Condition(s)

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

Pharmaceutical Form(s)

Solution for injection; Age appropriate pharmaceutical form

Route(s) of Administration

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 13/12/2023 09:56 GMT an application for a Modification

The procedure started on 12/02/2024 08:24 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 and to link this PIP with related PIP Decisions covering all authorised indications of risankizumab for treatment of psoriasis, for treatment of Crohn's disease, and for the treatment of ulcerative colitis, including all subsequent modifications thereof.

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-101250-PIP01-23-M01

Of 15/04/2024 10:24 BST

On the adopted decision for RISANKIZUMAB (MHRA-101250-PIP01-23-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, Solution for injection; Age appropriate pharmaceutical form , SUBCUTANEOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, 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 Age appropriate pharmaceutical form Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: For the paediatric population from birth to less than 1 year 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 the paediatric population from 1 year to less than 5 years of age: - on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, spondylarthritis and 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 Age appropriate pharmaceutical form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate pharmaceutical form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (M23-732) Open-label, randomised, assessor-blinded trial to evaluate efficacy, safety, tolerability and pharmacokinetics (PK) of subcutaneous risankizumab with an adalimumab reference arm in children from 5 years to less than 18 years of age with juvenile psoriatic arthritis (JIA-PsA).
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation study to predict risankizumab doses in children and adolescents from 5 years to less than 18 years of age with active juvenile psoriatic arthritis (JIA-PsA).
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:	31/07/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes