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-101198-PIP01-23-M01

Scope of the Application

Active Substance(s)

RISANKIZUMAB

Condition(s)

Treatment of Crohn's Disease

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 05/12/2023 11:21 GMT an application for a Modification

The procedure started on 12/02/2024 07:40 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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, spondylarthritis and juvenile idiopathic arthritis), 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-101198-PIP01-23-M01

Of 13/03/2024 09:20 GMT

On the adopted decision for RISANKIZUMAB (MHRA-101198-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, 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 Road, Maidenhead, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Crohn's Disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age 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 Reason for granting waiver: 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 Crohn's Disease

2.2 Indication(s) targeted by the PIP:

Treatment of moderately to severely active Crohn's disease

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

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

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Development of an age-appropriate paediatric formulation/ presentation for paediatric use for induction treatment. Study 2 Development of an age-appropriate paediatric formulation/ presentation for paediatric use for maintenance treatment.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 3 (M16-194) Study in paediatric patients from 2 years to less than 18 years of age with Crohn's disease (CD) to evaluate the efficacy, safety, and pharmacokinetics (PK) of risankizumab including a 12-week open label induction period followed by a randomised 52-week maintenance period.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation population PK study.
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:	31/03/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes