MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-100376-PIP01-21-M02

Scope of the Application

Active Substance(s)

VEDOLIZUMAB

Condition(s)

Treatment of ulcerative colitis, Treatment of Crohn's disease

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion, Solution for injection

Route(s) of Administration

INTRAVENOUS USE; SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

TAKEDA UK LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, TAKEDA UK LIMITED submitted to the licensing authority on 13/10/2024 19:23 BST an application for a Modification

The procedure started on 29/11/2024 15:37 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.

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-100376-PIP01-21-M02

Of 28/01/2025 15:37 GMT

On the adopted decision for VEDOLIZUMAB (MHRA-100376-PIP01-21-M02) 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 VEDOLIZUMAB, Powder for concentrate for solution for infusion, Solution for injection , INTRAVENOUS USE; SUBCUTANEOUS USE .

This decision is addressed to TAKEDA UK LIMITED, 1 Kingdom Street, London, UNITED KINGDOM, W2 6BD

ANNEX I

1. Waiver

1.1 Condition:

Condition 1: 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): Powder for concentrate for solution for infusion; Solution for injection Route(s) of administration: INTRAVENOUS USE; SUBCUTANEOUS USE Reason for granting waiver: On the grounds the specific medicinal product is likely to be unsafe Condition 2: Treatment of ulcerative colitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Powder for concentrate for solution for infusion; Solution for injection Route(s) of administration: INTRAVENOUS USE; SUBCUTANEOUS USE Reason for granting waiver: On the grounds the specific medicinal product is likely to be unsafe

2. Paediatric Investigation Plan:

2.1 Condition(s):

Condition 1: Treatment of Crohn's disease Condition 2: Treatment of ulcerative colitis

2.2 Indication(s) targeted by the PIP:

Condition 1: Treatment of moderately to severely active Crohn's disease. Condition 2: Treatment of moderately to severely active ulcerative colitis.

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

Condition 1: The paediatric population from 2 years to less than 18 years of age. Condition 2: The paediatric population from 2 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Powder for concentrate for solution for infusion Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 1 (MLN0002-2003) Randomised, double-blind, dose-ranging clinical pharmacology study to determine the pharmacokinetics, safety and tolerability of vedolizumab in paediatric subjects from 2 years to less than 18 years of age with ulcerative colitis or Crohn's disease. Study 2 (MLN0002-3025) Randomised, double-blind, multicentre study comparing two doses to evaluate the efficacy and safety of vedolizumab intravenous as maintenance therapy in paediatric subjects from 2 years to less than 18 years of age with moderately to severely active Crohn's disease who achieved clinical response following open-label vedolizumab intravenous therapy. Study 3 (MLN0002-3024) Randomised, double-blind, multicentre study comparing two doses to evaluate the efficacy, safety and pharmacokinetics of vedolizumab intravenous as

		maintenance therapy in paediatric subjects from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis who achieved clinical response following open-label vedolizumab intravenous therapy. Study 5 (VedolizumabSC-3003) (This study was added during procedure EMEA-000645-PIP01-09-M06) Open-Label study to determine the pharmacokinetics, safety and immunogenicity of vedolizumab subcutaneous (SC) use in paediatric subjects from 2 years to less than 18 years of age with ulcerative colitis or Crohn's disease.
Extrapolation, Modeling & Simulation Studies	1	Study 6 (This study was added during procedure EMEA-000645-PIP01-09-M06) Modelling and simulation study to evaluate use of vedolizumab via the subcutaneous route in children and adolescents from 2 years to less than 18 years of age with ulcerative colitis or Crohn's disease.
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:	30/09/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes