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

MHRA-100376-PIP01-21-M01

# Scope of the Application

## Active Substance(s)

VEDOLIZUMAB

## Condition(s)

Treatment of Crohn's Disease, Treatment of Ulcerative colitis

## 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 Pharma A/S, Dybendall Alle 10, 2630 Taastrup, Denmark

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Takeda Pharma A/S, Dybendall Alle 10, 2630 Taastrup, Denmark submitted to the licensing authority on 26/11/2021 05:31 GMT an application for a Modification

The procedure started on 01/09/2022 08:51 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 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-M01

Of 21/09/2022 07:46 BST

On the adopted decision for VEDOLIZUMAB (MHRA-100376-PIP01-21-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 VEDOLIZUMAB, Powder for concentrate for solution for infusion, Solution for injection , Intravenous use, Subcutaneous use .

This decision is addressed to Takeda Pharma A/S, Dybendall Alle 10, 2630 Taastrup, Denmark, Dybendall Alle 10, Taastrup, Denmark, 2630

# 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 that 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 that the specific medicinal product is likely to be unsafe.

## 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

Condition1: 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):

Condition 1: Powder for concentrate for solution for infusion; Solution for injection. Condition 2: Powder for concentrate for solution for infusion; Solution for 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** | 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 (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 (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:** | 30/06/2027 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |