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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100068-PIP01-21

Scope of the Application

Active Substance(s)

VEDOLIZUMAB

Condition(s)

Treatment of Pouchitis

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

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Takeda Pharma A/S submitted to the licensing authority on 31/03/2021 15:53 BST an application for a Paediatric Investigation Plan

The procedure started on 12/11/2021 12:01 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-100068-PIP01-21

Of 26/11/2021 07:29 GMT

On the adopted decision for VEDOLIZUMAB (MHRA-100068-PIP01-21) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan 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, Delta Park 45, Vallensbaek Strand, Denmark, 2665

ANNEX I

1. Waiver

1.1 Condition:

Treatment of pouchitis 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 disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of pouchitis

2.2 Indication(s) targeted by the PIP:

Treatment of active pouchitis

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):

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	1	Study 1 Open label, single-arm trial to evaluate the tolerability, pharmacokinetics and immunogenicity of intravenous vedolizumab in children from 2 years to less than 18 years of age with active pouchitis.
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:	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