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 (MHRA-100361-PIP01-21-M01)

MHRA-100361-PIP01-21-M02

Scope of the Application

Active Substance(s)

GOLIMUMAB

Condition(s)

Treatment of ulcerative colitis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 05/12/2022 13:58 GMT an application for a Modification

The procedure started on 01/03/2023 10:31 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

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-100361-PIP01-21-M02

Of 16/03/2023 08:26 GMT

On the adopted decision for GOLIMUMAB (MHRA-100361-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 GOLIMUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, UNITED KINGDOM, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

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): Solution for injection Route(s) of administration: 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 ulcerative colitis

2.2 Indication(s) targeted by the PIP:

Treatment of ulcerative colitis

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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate paediatric presentation.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 A multicentre, open-label study to assess the PK and safety of golimumab treatment in patients from 2 years to less than 18 years old with moderately to severely active ulcerative colitis. Study 3 Deleted during procedure EMEA 000265-PIP02-11-M02. Study 4 (added during procedure EMEA 000265-PIP02-11-M02) Randomised, open-label golimumab study in paediatric patients from 2 years to less than 18 years with moderately to severely active ulcerative colitis.
Extrapolation, Modeling & Simulation Studies	3	Study 5 (added during procedure EMEA 000265-PIP02-11-M02) Population pharmacokinetic (PK) modelling and simulation study. Study 6 (added during procedure EMEA 000265-PIP02-11-M02) Exposure-response modelling and simulation study. Study 7 (added during procedure EMEA 000265-PIP02-11-M02) Analysis of internal and literature data to support the assumptions of similarity of disease, treatment effects, and exposure-response relationship between

		paediatric and adult subjects with ulcerative colitis (UC).
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:	31/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes