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-100511-PIP01-22-M01

Scope of the Application

Active Substance(s)

GUSELKUMAB

Condition(s)

Treatment of Crohn's Disease

Pharmaceutical Form(s)

Solution for injection in pre-filled pen; Solution for injection in pre-filled syringe; Solution for injection

Route(s) of Administration

Subcutaneous use; Intravenous use

Name / Corporate name of the PIP applicant

Janssen - Cilag Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen - Cilag Ltd submitted to the licensing authority on 18/05/2022 15:38 BST an application for a Modification

The procedure started on 10/08/2022 12:05 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-100511-PIP01-22-M01

Of 24/08/2022 16:12 BST

On the adopted decision for GUSELKUMAB (MHRA-100511-PIP01-22-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 GUSELKUMAB, Solution for injection in pre-filled pen; Solution for injection in pre-filled syringe; Solution for injection , Subcutaneous use; Intravenous use .

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

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): Solution for injection in pre-filled pen; Solution for injection in pre-filled syringe; Solution for injection Route(s) of administration: Subcutaneous use; Intravenous 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 in paediatric subjects from 2 to less than 18 years of age with, who have had an inadequate response, lost response, or were intolerant to either conventional therapy or biologic therapy

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 in pre-filled pen; Solution for injection in pre-filled syringe; 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 (CNTO1959PBCRD3007) Randomised, open-label induction treatment period in which patients receive intravenous (IV) or subcutaneous (SC) guselkumab induction dosing, followed by a randomised, double-blind, 2-arm maintenance treatment period in which all patients receive SC guselkumab dosing (two different dose levels) to assess pharmacokinetics (PK), efficacy, and safety in paediatric subjects from 2 years to less than 18 years of age with moderately to severely active Crohn's disease.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Extrapolation/interpolation population PK model. Study 3 Extrapolation/interpolation exposure response model.
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:	31/01/2028

Deferral of one or more studies contained in the paediatric investigation plan:	Yes