**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 (MHRA-100321-PIP01-21-M01)

MHRA-100779-PIP01-22-M01

# Scope of the Application

## Active Substance(s)

GUSELKUMAB

## Condition(s)

Treatment of chronic idiopathic arthritis (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

## 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 28/12/2022 16:59 GMT an application for a Modification

The procedure started on 23/05/2023 16:04 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

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-100779-PIP01-22-M01

Of 15/06/2023 17:13 BST

On the adopted decision for GUSELKUMAB (MHRA-100779-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 , 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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis). The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible. |

## 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis). |

## 2.2 Indication(s) targeted by the PIP:

| |
|---|
| Treatment of juvenile psoriatic arthritis |

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

| |
|---|
| The paediatric population from 5 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** | 0 | Not applicable. |
| **Non-Clinical Studies** | 0 | Not applicable. |
| **Clinical Studies** | 1 | Study 1 (CNTO1275JPA3001) Open-label trial to evaluate pharmacokinetics, safety, efficacy and immunogenicity of guselkumab in children from 5 years to less than 18 years of age with active juvenile psoriatic arthritis (jPsA) despite DMARD therapy. |
| **Extrapolation, Modeling & Simulation Studies** | 2 | Study 2 Modelling and simulation study to evaluate the use of guselkumab in children from 5 years to less than 18 years of age with active juvenile psoriatic arthritis (jPsA) despite DMARD therapy. Study 3 Extrapolation study to evaluate the use of guselkumab in children from 5 years to less than 18 years of age with active juvenile psoriatic arthritis (jPsA) despite DMARD therapy. |
| **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:** | 30/06/2031 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |