**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

MHRA-100293-PIP01-21

# Scope of the Application

## Active Substance(s)

lenzilumab

## Condition(s)

Treatment of coronavirus disease 2019 (COVID-19)

## Pharmaceutical Form(s)

Concentrate for solution for injection/infusion

## Route(s) of Administration

Intravenous use

## Name / Corporate name of the PIP applicant

Humanigen Limited

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Humanigen Limited submitted to the licensing authority on 01/10/2021 12:37 BST an application for a Paediatric Investigation Plan

The procedure started on 26/10/2021 11:05 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 agree a paediatric investigation plan and grant a 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-100293-PIP01-21

Of 05/05/2022 07:51 BST

On the adopted decision for lenzilumab (MHRA-100293-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 lenzilumab, Concentrate for solution for injection/infusion , Intravenous use .

This decision is addressed to Humanigen Limited, 5 Fleet Place, London, United Kingdom, EC4M 7RD

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Not applicable |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of coronavirus disease 2019 (COVID-19) |

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

| |
|---|
| Treatment of patients hospitalised with coronavirus disease 2019 (COVID-19) |

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

| |
|---|
| All subsets of the paediatric population from birth to less than 18 years of age |

## 2.4 Pharmaceutical Form(s):

| |
|---|
| Concentrate for solution for injection/infusion |

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 0 | Not applicable |
| **Non-Clinical Studies** | 1 | Study 1 Enhanced pre- and postnatal development (ePPND) study of Lenzilumab in cynomolgus monkeys . |
| **Clinical Studies** | 2 | Study 2 Open-label, single arm trial to assess the safety, tolerability, pharmacokinetics (PK), and efficacy of intravenous lenzilumab, in adolescent patients from 12 years to less than 18 years of age hospitalised for treatment of confirmed COVID-19. Study 3 Open-label, single arm, single-dose study to evaluate the safety, tolerability, pharmacokinetics (PK) and efficacy of lenzilumab, for the treatment of paediatric patients from birth to less than 12 years of age hospitalised with laboratory confirmed COVID-19. |
| **Extrapolation, Modeling & Simulation Studies** | 4 | Study 4 (M&S-001) Population PK (popPK) modelling and simulation study to characterise the pharmacokinetics (PK) of lenzilumab, to perform dosing prediction and confirmation in adolescents from 12 years to less than 18 years of age. Study 5 (M&S-002) Population PK/ PD modelling study to support extrapolation of efficacy from adults to adolescent patients (from 12 year to less than 18 years of age) using data from the clinical trial in adolescents together with available data in adult COVID patients. Study 6 (M&S-003) Population PK/PD modelling and simulation study to support lenzilumab dosing prediction and confirmation in children aged from birth to less than 12 years of |

| | | |
|---|---|---|
| | | age. Study 6 (M&S-004) Population PK/PD modelling and simulation study to support the extrapolation of efficacy from adults and adolescents to children from birth to less than 12 years of age. |
| **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:** | 31/12/2028 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |