**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-100235-PIP01-21-M02) and to the deferral and a proposed waiver

MHRA-100235-PIP01-21-M03

# Scope of the Application

## Active Substance(s)

SOTROVIMAB

## Condition(s)

Treatment of coronavirus disease 2019 (COVID-19)

## Pharmaceutical Form(s)

Concentrate for solution for infusion

## Route(s) of Administration

INTRAVENOUS USE

## Name / Corporate name of the PIP applicant

GLAXOSMITHKLINE UK LIMITED

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GLAXOSMITHKLINE UK LIMITED submitted to the licensing authority on 27/09/2024 12:41 BST an application for a Modification

The procedure started on 25/10/2024 10:11 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 and a proposed 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-100235-PIP01-21-M03

Of 30/10/2024 15:28 GMT

On the adopted decision for SOTROVIMAB (MHRA-100235-PIP01-21-M03) 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 SOTROVIMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to GLAXOSMITHKLINE UK LIMITED, 980 Great West Road, Brentford, UNITED KINGDOM, TW8 9GS

# ANNEX I

## 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of coronavirus disease 2019 (COVID-19). The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s). |

## 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 paediatric patients with COVID-19 who are at risk of progressing to severe disease. |

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

| |
|---|
| The paediatric population from 6 years of age to less than 18 years of age. |

## 2.4 Pharmaceutical Form(s):

| |
|---|
| Concentrate for solution for infusion. |

## 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 (215226) Open-label, non-comparator, multicentre study to describe pharmacokinetics (PK), pharmacodynamics (viral load) and safety following a single intravenous dose of sotrovimab in paediatric participants from 6 years of age to less than 18 years of age with mild to moderate COVID-19 at high risk of progression. |
| **Extrapolation, Modeling & Simulation Studies** | 1 | Study 2 Population PK (PopPK) model for dosing prediction and confirmation in paediatric patients from 12 years of age to less than 18 years of age. Study 3, deleted in procedure MHRA-100235-PIP01-21-M03. |
| **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:** | 30/11/2023 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |