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-M01) and to the deferral

MHRA-100235-PIP01-21-M02

Scope of the Application

Active Substance(s)

SOTROVIMAB; 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 27/02/2023 11:52 GMT an application for a Modification

The procedure started on 23/05/2023 16:14 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-100235-PIP01-21-M02

Of 21/09/2023 15:24 BST

On the adopted decision for SOTROVIMAB (MHRA-100235-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 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:

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 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:

All subsets of the paediatric population from birth 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 the pharmacokinetics (PK), pharmacodynamics (viral load) and safety following a single intravenous (IV) dose of sotrovimab in paediatric participants with mild to moderate COVID-19 at high risk of progression.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population PK (PopPK) model for dosing prediction and confirmation in paediatric patients from 32 weeks of gestational age (GA) (at birth) to less than 18 years of age. Study 3 PK bridging and extrapolation of safety and virology data to support the use of sotrovimab for the treatment of mild, moderate COVID-19 in children from 32 weeks gestational age (at birth) to less than 18 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:	31/10/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes