# An open-label, non-comparator, multicenter study to describe the pharmacokinetics (PK), pharmacodynamics (PD; viral load) and safety following a single intravenous or intramuscular dose of sotrovimab in pediatric participants with mild to moderate COVID-19 at high risk of disease progression (COMET-PACE) (215226)

**First published:** 03/05/2022

**Last updated:** 29/05/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS47006

**Study ID**

47007

**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study description**

This study is a Phase 2b open-label, non-comparator, multi-center study to evaluate pharmacokinetics (PK), safety, and pharmacodynamics (PD) of sotrovimab administered via intravenous (IV) infusion or intramuscular (IM) injection in pediatric participants (aged from birth to <18 years) with mild-to-moderate COVID-19 at high risk of disease progression. Participants will be enrolled in one of two cohorts (Cohort A or Cohort B). Participants in Cohort A will receive IV sotrovimab and participants in Cohort B will receive sotrovimab via an IM injection. Cohort A and Cohort B will each enroll approximately 36 participants, therefore, a total of approximately 72 participants will be enrolled in this study. The countries that are included in the end are Brazil, Colombia, Greece, Philippines, South Africa, and USA.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### GlaxoSmithKline (GSK)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

**Study institution contact**

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

**Primary lead investigator**

GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 12/08/2021

**Study start date**

Planned: 18/12/2021

Actual: 16/12/2021

**Date of final study report**

Planned: 08/05/2024

Actual: 09/10/2023

## Sources of funding

- Other

## More details on funding

GlaxoSmithKline and VIR Biotechnology

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

NCT05124210

Link to Clinicaltrials.gov

# Methodological aspects

## Study type

## Study type list

**Study type:**

Clinical trial

**Main study objective:**

To evaluate the pharmacokinetics by IV or IM administration of sotrovimab in children from birth to <18 years. To evaluate the safety and tolerability of sotrovimab by IV or IM administration.

## Study drug and medical condition

**Medicinal product name**

XEVUDY

**Medicinal product name, other**

Sotrovimab

**Study drug International non-proprietary name (INN) or common name**

SOTROVIMAB

**Anatomical Therapeutic Chemical (ATC) code**

(J06BD05) sotrovimab

sotrovimab

**Medical condition to be studied**

COVID-19

## Population studied

**Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

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**Estimated number of subjects**

72

## Study design details

**Data analysis plan**

Full details of all analysis methods for the exploratory endpoints will be provided in the statistical analysis plan.

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data sources (types)**

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No