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

PURI

https://redirect.ema.europa.eu/resource/47007

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

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

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

Name of medicine

XEVUDY

Name of medicine, 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)

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

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