XEVUDY General Drug Use Investigation (SARS-CoV-2 Infection) - COVID-19 (217893)

First published: 03/04/2023

Last updated: 25/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/103975

EU PAS number

EUPAS103974

Study ID

103975

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This study aims to collect and assess information about safety and effectiveness of XEVUDY in participants with severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) infection who have risk factors for progression to severe SARS-CoV-2 infection and do not require oxygen administration (OA) in daily clinical practice. XEVUDY is a registered trademark of GlaxoSmithKline group of companies.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

SHOWA University Hospital Tokyo, Japan

Contact details

Study institution contact

Call Center EU GSK Clinical Trials

Study contact

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Primary lead investigator

Call Center EU GSK Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/06/2020

Study start date

Planned: 28/02/2022

Actual: 07/02/2022

Date of final study report

Planned: 31/12/2024

Actual: 06/11/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline (GSK), Vir Biotechnology (VIR)

Study protocol

Sotrovimab_PMS_Protocol_in_Japan_Anonymized.pdf(268.1 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Safety and clinical outcomes

Main study objective:

The objective of this study is to collect and assess the following information about safety and clinical outcomes of Xevudy in patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection who have risk

factors for progression to severe SARS-CoV-2 infection and do not require oxygen administration (OA) in daily clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XEVUDY

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

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

630

Study design details

Outcomes

Occurrence status of adverse drug reactions (ADRs), Proportion of non-responders, and distribution and transition of vital signs and clinical symptoms.

Data analysis plan

The incidence rate of adverse drug reactions (ADR) in participants will be calculated throughout the period of 29 days. The proportion of non-responders will be calculated (from Day 1 to the end of the observation period). The proportion of participant outcomes at the end of the observation period in participants other than non-responders will be calculated. The Robust (modified) Poisson regression model will be used to calculate the risk ratio and 95% confidence interval for each factor likely to affect safety (incidence rate of ADR participants) and clinical outcomes (proportion of non-responders), and to

explore risk factors.

Documents

Study report

Sotrovimab PMS 217893 final report Anonymized 18 Apr 2024.pdf(3.28 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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