A Cohort Study to Evaluate the Real-World Utilization and Effectiveness of Bebtelovimab Compared to Paxlovid among Patients with Mild-to-Moderate COVID-19 Who Are at High Risk for Progressing to Severe Illness (J2X-MC-B003)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50701

EU PAS number

EUPAS50700

Study ID

50701

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

TriNetX

Belgium

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Institution | Non-Pharmaceutical company

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elsie Grace

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 27/04/2022

Study start date
Planned: 15/02/2023

Actual: 15/02/2023

Date of final study report
Planned: 31/07/2023

Actual: 21/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY3853113 J2X-MC-B003 RWE Protocol_Redacted.pdf(1.45 MB)

LY3853113 J2X-MC-B003(a) RWE Protocol_Redacted.pdf(1.31 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To estimate the 30-day risk difference of the composite outcome of all-cause hospitalization or all-cause death for patients who received bebtelovimab compared to patients who received Paxlovid.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

PAXLOVID

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

BEBTELOVIMAB

NIRMATRELVIR

RITONAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AE30) nirmatrelvir and ritonavir

nirmatrelvir and ritonavir

Medical condition to be studied

SARS-CoV-2 test positive

Additional medical condition(s)

Positive results of direct SARS-CoV-2 viral testing and high risk for progression to severe 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)

Estimated number of subjects

2780

Study design details

Outcomes

All-cause hospitalization or all-cause death, 30-day risk difference of all-cause hospitalization, all-cause death, and all-cause emergency department visits.

Data analysis plan

For patients included in both study cohorts, descriptive statistics will be used to describe baseline characteristics. Differences between baseline characteristics will be calculated using standardized differences before and after propensity score matching. An intent-to-treat approach will be used to derive the cumulative incidence (risk) and risk difference and 95% CI of 30-day all-cause hospitalization or all-cause death (primary analysis composite outcome). For comparing the outcomes between the 2 cohorts, confounding control will be achieved using coarsened exact matching on highly selected and a priori defined baseline variables in conjunction with propensity score matching on a broader set of baseline variables. For the primary analysis only, the noninferiority null hypothesis for this objective will be tested using the 1-sided Type I error of 0.025 by setting the RDUCL 95% CI of the bebtelovimab versus Paxlovid to be less than the prespecified noninferiority margin of 1.795%.

Documents

Study report

LY3853113_J2X-MC-B003 Full Clinical Study Report_Redacted.pdf(2.71 MB)

Data management

Data sources

Data source(s), other

TriNetX Dataworks USA Network, United States

TriNetX Linked Network (Supplemental Data Source)

Data sources (types)

Administrative healthcare records (e.g., claims)

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