TAK-620-4007: Retrospective Chart Review of Safety Outcomes Associated With Use of Maribavir in Patients With Post-transplant Refractory Cytomegalovirus (CMV) Infection and Comorbid Endstage Renal Disease (ESRD) or Comorbid Severe Chronic Renal Disease Requiring Peritoneal Dialysis or Hemodialysis

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000006

EU PAS number

EUPAS1000000006

Study ID

1000000006

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

The main aim of this study is to assess the safety profile of maribavir when treating refractory cytomegalovirus (CMV) infection after transplantation in adults with kidneys that are no longer functioning on their own (also called end-stage renal disease or ESRD) or have severe chronic kidney disease requiring artificial filtering of the kidney (dialysis) or the blood (hemodialysis).

In this study, already existing data will be collected from the participant’s medical records. The study will only review data collected as part of the normal clinical routine and will not impact the standard medical care and treatment of participants.

Study status

Planned

Contact details

Study institution contact

Study Contact Takeda

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/05/2025

Study start date

Planned: 30/06/2025

Data analysis start date

Planned: 01/09/2025

Date of interim report, if expected

Planned: 30/09/2025

Date of final study report

Planned: 31/01/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

TAK-620-4007 PASS Protocol 02Jun2023 SR_Redacted.pdf(682.19 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To characterize the safety profile of maribavir when treating refractory cytomegalovirus (CMV) infection after transplantation in adults with end-stage renal disease or severe chronic kidney disease requiring peritoneal dialysis or hemodialysis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

LIVTENCITY

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

MARIBAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AX) Other antivirals

Other antivirals

Additional medical condition(s)

Kidney failure

Population studied

Age groups

Adult and elderly population (≥18 years)

Special population of interest

Renal impaired

Estimated number of subjects

10

Study design details

Outcomes

The primary outcomes will assess the number of participants with adverse events (AEs). The secondary outcomes will assess the number of participants with adverse events of special interest (AESIs).

Data analysis plan

The statistical analysis of the data will be primarily descriptive. Continuous variables will be described by the number of eligible participants and missing data, mean, standard deviation or standard error, median, first quartile, third quartile, and minimum and maximum values. Categorical variables will be described by the total number of participants and relative proportion per category.

Data management

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