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 Severe Chronic Kidney Disease (CKD) or Comorbid End-stage Renal Disease (ESRD), Including Patients on Peritoneal Dialysis or Hemodialysis

First published: 01/03/2024

Last updated: 01/07/2025

Study Planned

Administrative details

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 of maribavir in adults with severe CKD or comorbid ESRD including participants on 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

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

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: 30/11/2025

Data analysis start date

Planned: 01/01/2026

Date of interim report, if expected
Planned: 28/02/2026

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

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is an observational, multi country, retrospective, post-authorization safety study (PASS)
based on the review of secondary data collected from medical records of transplant recipients.

Main study objective:

To characterize the safety of maribavir as prescribed in routine clinical practice in terms of occurrence of adverse events (AE) in patients with post-transplant refractory CMV infection and comorbid severe CKD or comorbid ESRD, including participants on 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

Short description of the study population

Participants treated with maribavir for a refractory (with or without resistance) CMV infection and who have severe CKD or comorbid ESRD including participants on peritoneal dialysis or hemodialysis.

Age groups

Adult and elderly population (≥18 years)

Special population of interest

Frail population

Immunocompromised

Renal impaired

Estimated number of subjects

10

Study design details

Setting

This proposed retrospective study will be conducted among eligible patients aged 18 years or older on maribavir treatment with comorbid severe CKD or ESRD within routine clinical practice settings. The source population will comprise of eligible patients across nine European nations. Included patients will contribute data from the start of eligible maribavir treatment to completion, discontinuation, end of study or death, whichever comes first. Data accrual will vary between countries, depending on their respective launch dates for maribavir.

Comparators

None

Outcomes

The primary outcome is to 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, 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

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)

Non-interventional study

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

Unknown