Belzutifan special drug use results survey in radically unresectable or metastatic renal cell carcinoma: a postauthorization safety study (PASS) (MK-6482-045)

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Study | Planned

Administrative details

EU PAS number

EUPAS1000000880

Study ID

1000000880

DARWIN EU® study

No

Study countries

Japan

Study description

This study will describe adverse events (AEs) in patients with radically unresectable or metastatic renal cell carcinoma (RCC) who are treated with belzutifan in routine practice. The main objective of this study is to monitor the risk of occurrence of hemorrhages and fractures during the administration of belzutifan in patients with RCC.

Study status

Planned

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution **Pharmaceutical company**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/07/2025

Study start date
Planned: 30/04/2026

Data analysis start date
Planned: 28/03/2031

Date of final study report
Planned: 27/05/2032

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

6482-045-01-v0-with-ha-approval-date_final-redaction.pdf (464.79 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a non-interventional, descriptive, longitudinal, multicenter collaborative study in Japan of patients with radically unresectable or metastatic RCC treated with belzutifan.

Main study objective:

To evaluate the risk of occurrence of hemorrhages and fractures during the administration of belzutifan in Japanese patients with radically unresectable or metastatic RCC.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive, longitudinal, multi-center collaborative study

Study drug and medical condition

Medicinal product name

WELIREG

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

BELZUTIFAN

Anatomical Therapeutic Chemical (ATC) code

(L01XX74) belzutifan

belzutifan

Medical condition to be studied

Renal cell carcinoma

Population studied

Short description of the study population

Patients in Japan with radically unresectable or metastatic RCC (not Von Hippel-Lindau disease (VHL)-associated) who received belzutifan in routine clinical practice for the first time, according to the local Japanese label of belzutifan.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

403

Study design details

Setting

Japanese patients with radically unresectable or metastatic RCC (not VHL-associated), treated with belzutifan for the first time in routine clinical practice according to the local label. Enrollment may occur prospectively at treatment initiation or retrospectively after treatment initiation but before the end of the registration period. There are no comparator arms. Patient and treatment data will be sourced from the patient medical records.

Comparators

There are no comparator arms.

Outcomes

The primary outcomes of interests are:

- Number of participants who experience a hemorrhagic AE
- Number of participants who experience a fracture AE

Data analysis plan

Study endpoints will be analyzed using descriptive statistical methods such as mean, standard deviation, median, interquartile range, and/or minimum/maximum/range for continuous variables. For any categorical variables, e.g., AE analysis, frequency and percentage will be reported. There is no hypothesis testing. To assess whether demographic and/or clinical characteristics impact safety endpoints, these characteristics will be analyzed using descriptive statistical methods and reported for all registered subjects, the safety evaluation group, and presence/absence of AEs/select protocol-specified AEs.

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)

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