Belzutifan special drug use results survey in von Hippel-Lindau (VHL) disease-associated tumors: a post-authorization safety study (PASS) (MK-6482-046)

First published: 20/02/2026

Last updated: 15/04/2026

Study | Planned

Administrative details

EU PAS number

EUPAS1000000881

Study ID

1000000881

DARWIN EU® study

No

Study countries

Japan

Study description

The purpose of this study is to collect/ascertain more completely the number of adverse events (AEs) in the local Japanese population and describe the AEs among Japanese subjects with von Hippel-Lindau (VHL) disease-associated tumors treated with belzutifan in routine clinical practice in accordance with the local regulation. The primary objective is to monitor the risk of occurrence of hemorrhages and fractures during the administering of belzutifan in subjects with VHL disease-associated tumors. The secondary objectives are to assess the overall safety of belzutifan, including safety specifications, in subjects with VHL disease-related tumors, and the effectiveness of belzutifan in subjects with VHL disease-associated tumors.

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: 31/03/2032

Date of final study report

Planned: 13/05/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

6482-046-01-v0-with-ha-approval-date_final-redaction.pdf (527.14 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, multi-center collaborative study. The study includes subjects in Japan with von Hippel-Lindau (VHL) disease-associated tumors who have received belzutifan in routine clinical practice as indicated by the current local label.

Main study objective:

The main objective of this study is to monitor the occurrence of hemorrhages and fractures in Japanese subjects with VHL disease associated tumors receiving belzutifan in routine clinical practice. This study will also describe the overall safety and effectiveness of belzutifan in this population.

Study Design

Non-interventional study design

Cohort

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

Von Hippel-Lindau disease

Population studied

Short description of the study population

The study population includes adult Japanese patients (>=15 years of age) with VHL disease associated tumors who received belzutifan for the first time following its approval on 24 June 2025 in Japan, as part of routine clinical practice and in accordance with the local label. Patients are observed from the start of belzutifan administration through the treatment period, with adverse events collected during treatment and for 30 days after treatment discontinuation. The total observation period is up to 24 months or 104 weeks from the first belzutifan administration.

Age groups

- Adolescents (12 to < 18 years)
- **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

69

Study design details

Setting

Adult Japanese subjects (>=15 years) with VHL disease associated tumors who received belzutifan for the first time following its approval on 24 June 2025 in routine clinical practice.

Outcomes

The primary outcome for the study will be safety specifically the risk of hemorrhage and fractures during administration of belzutifan in subjects with VHL disease-associated tumors. Safety will be evaluated using investigator-reported adverse events (AEs), including all AEs, adverse drug reactions (ADRs), serious adverse events (SAEs), serious adverse drug reactions (SADRs), and grade 3-5 AEs and ADRs.

Data analysis plan

Study endpoints will be analyzed using descriptive statistical methods. For continuous variables, mean, standard deviation, median, interquartile range, and minimum-maximum will be reported. For categorical variables, including AEs, frequency and percentage distributions will be presented. Cross-tabulations may also be used. Demographic and clinical characteristics will be

summarized descriptively for all registered subjects and the safety analysis set, and for the presence or absence of AEs, including select protocol-specified AEs. Continuous and count variables may also be categorized into ranges and described using frequency and percentage distributions. No hypothesis testing or imputation of missing data will be performed.

Subject characteristics and frequency of the outcomes of interest will be described using frequency and percentage (cross-tabulations may also be included) for categorical variables and descriptive statistics (mean, standard deviation, min, max, median, interquartile range) for continuous and count variables. Continuous and count variables may also be categorized into ranges and described using frequency and percentage distributions. Descriptive summaries will be provided for all registered subjects and, separately, the safety analysis set (if different from all registered subjects).

The severity, outcomes, seriousness criteria and action taken with belzutifan of AEs, ADRs, SAEs, SADRs will be summarized descriptively.

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