

# A post-licensure prospective observational registry study in real-world Taiwanese cancer patients with microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) genes

**First published:** 10/03/2020

**Last updated:** 17/12/2024

Study

Discontinued

## Administrative details

### EU PAS number

EUPAS33807

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### Study ID

47306

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### DARWIN EU® study

No

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### Study countries

 Taiwan

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## Study description

In major cancer centers in Taiwan, participants with a diagnosis of advanced unresectable or metastatic solid tumors and have progressed on prior standard therapy following index diagnosis will be screened for microsatellite instability (MSI)/deoxyribonucleic (DNA) mismatch repair (MMR) status. Participants that test MSI-H (including deficient mismatch repair dMMR) positive and receive at least one dose of pembrolizumab will be enrolled following consent and prospectively followed through a registry. The primary objectives of the study are to measure objective response rate (ORR) and duration of response (DOR) in participants who have received at least 1 dose of pembrolizumab.

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## Study status

Discontinued

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

 United States

**First published:** 01/02/2024

**Last updated:** 08/07/2025

Institution

Pharmaceutical company

## Contact details

### **Study institution contact**

Clinical Trials Disclosure Merck Sharp & Dohme LLC  
ClinicalTrialsDisclosure@merck.com

Study contact

[ClinicalTrialsDisclosure@merck.com](mailto:ClinicalTrialsDisclosure@merck.com)

### **Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 21/04/2020

Actual: 21/01/2020

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### **Study start date**

Planned: 01/10/2021

Actual: 01/10/2021

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### **Data analysis start date**

Actual: 15/09/2023

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### **Date of final study report**

Planned: 13/12/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme LLC

## Study protocol

[MK-3475-A80-00-v1-Protocol\\_Final Redaction.pdf](#) (4.16 MB)

[3475-A80-01-V2-Protocol\\_L1-final-redaction.pdf](#) (1.47 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

The main objectives are to describe demographic and clinicopathological characteristics and to describe objective response rate and duration of response in Taiwanese participants with advanced unresectable or MSI-H or dMMR cancers and who have progressed on prior standard therapy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

KEYTRUDA

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

PEMBROLIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01XC18) pembrolizumab

pembrolizumab

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**Medical condition to be studied**

Microsatellite instability cancer

## Population studied

## **Age groups**

- 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)
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## **Estimated number of subjects**

20

# Study design details

## **Outcomes**

The primary outcomes are the demographic and clinicopathological characteristics, objective response rate (ORR), and duration of response (DOR). The secondary outcomes are treatment-emergent adverse events (TEAEs) as reported during routine clinical care, progression-free survival (PFS), and overall survival (OS).

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## **Data analysis plan**

Descriptive analysis, including univariate analyses and cross tabulations, will be used for presenting baseline demographic and clinicopathological characteristics of the MSI-H/dMMR participants included in this study. ORR is defined as the combined proportion of participants with a Complete Response (CR) or Partial Response (PR) tumor response per the investigator's assessment, presented as a percentage with corresponding 95% confidence interval (CI). DOR is measured from the time of initial response until the time at which it is determined that tumor progression occurs. Kaplan-Meier plots will be generated to describe DOR with median DOR estimated along with the corresponding 95%

CI.

## 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)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No