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

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Last updated: 17/12/2024

Study Discontinued

Administrative details

EU PAS number

EUPAS33807

Study ID

47306

DARWIN EU® study

No

Study countries

☐ Taiwan

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.

Study status

Discontinued

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

Planned: 21/04/2020

Actual: 21/01/2020

Study start date

Planned: 01/10/2021

Actual: 01/10/2021

Data analysis start date

Actual: 15/09/2023

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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

PEMBROLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01XC18) pembrolizumab

pembrolizumab

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)

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).

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No