Real-world effectiveness of pembrolizumab among patients with TMB-H advanced solid tumors (MK-3475-G34)

First published: 06/05/2025

Last updated: 06/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000542

Study ID

1000000542

DARWIN EU® study

No

Study countries

United States

Study description

The main objective of the study is to understand the real-world effectiveness of pembrolizumab monotherapy among patients with advanced solid tumors with Tumor Mutational Burden-High (TMB-H) assayed by F1/F1CDx. This study will describe the real-world effectiveness of pembrolizumab monotherapy among adult patients with advanced solid tumors with TMB-H in 2nd line or 2nd line+ (2L/2L+) setting.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

Networks

Flatiron

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: 20/11/2024

Actual: 20/11/2024

Study start date

Planned: 02/05/2025

Actual: 02/05/2025

Data analysis start date

Planned: 31/12/2026

Date of final study report

Planned: 15/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study design:

It is an observational retrospective secondary data collection study using a structured licensed dataset delivered by Flatiron.

Main study objective:

The main objective of the study is to describe real-world effectiveness of pembrolizumab among patients with advanced solid tumors with TMB-H assayed by F1/F1CDx and to stratify by TMB cutoff points, tumor types when feasible.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational retrospective secondary data collection study

Study drug and medical condition

Medicinal product name

KEYTRUDA

Medicinal product name, other

Pembrolizumab

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

PEMBROLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FF02) pembrolizumab

pembrolizumab

Medical condition to be studied

Neoplasm malignant

Population studied

Short description of the study population

Adult patients with advanced/metastatic solid tumors, who were TMB-H (>=10 mut/mb, tested by FoundationOne CDx (F1/F1CDx) and non-microsatellite instability-high (non-MSI-H), and received pembrolizumab monotherapy in 2nd line or 2nd line+ (2L/2L+) setting.

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

368

Study design details

Setting

Adult patients with advanced/metastatic solid tumors included in the Flatiron Health-Foundation Medicine Clinical Genomic Database (CGDB).

Comparators

N/A

Outcomes

The primary endpoint is real-world response rate (rwRR), which is the proportion of the patients in the analysis population who had real-world complete response (rwCR) or real-world partial response (rwPR).
Secondary endpoint is real-world duration of response (rwDOR): in the subset of patients with a rwCR or rwPR, the time from first documented evidence of rwCR or rwPR until the first documented sign of disease progression, or death due to any cause, whichever occurs first.

Data analysis plan

The analyses will be of descriptive nature in this study. Baseline characteristics (at index date) of the study population will be described including demographics, disease stage, prior treatment, Eastern Cooperative Oncology Group (ECOG), biomarker status (TMB, MSI). Duration of follow-up will also be described.
For the study endpoints, analyses will be conducted across all tumor types as well as by tumor type, by TMB cutoff points, and by TMB within each tumor type, when feasible. Point estimates and exact Clopper-Pearson Confidence Intervals (CIs) will be provided.

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 source(s), other

Flatiron Health-Foundation Medicine Clinical Genomic Database (CGDB)

Data sources (types)

Disease registry

Drug prescriptions

Non-interventional study

Population registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes