Real-world post-authorization effectiveness study (PAES) of pembrolizumab for the treatment of NSCLC across races, ethnicities, and age groups (MK-3475-G18)

First published: 03/06/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000576

Study ID

1000000576

DARWIN EU® study

No

Study countries

United States

Study description

This is a real-world post-authorization effectiveness study (PAES) to characterize the real world effectiveness of pembrolizumab for the treatment of non-small cell lung cancer (NSCLC) among United States (US) patients across races, ethnicities, and age groups to address part of an FDA post-marketing commitment (PMC) for KEYNOTE-671 (4531-2).
The primary objectives are as follows:
(1) To evaluate the real-world effectiveness of pembrolizumab monotherapy in US NSCLC patients by estimating real-world overall survival (rwOS) among the following subgroups: Race (racial minorities [e.g., Black or African American, Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and Other Race] and white patients), Hispanic/Latino ethnicity (Hispanic/Latino patients and not Hispanic/Latino patients), and Age (elderly patients ≥75 years and younger patients <75 years).
(2) To evaluate the real-world effectiveness of pembrolizumab in combination with platinum-based chemotherapy in US NSCLC patients by estimating rwOS among the following subgroups: Race, Hispanic/Latino ethnicity, and Age.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

Flatiron Health, Inc.

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

ClinicalTrialsDisclosure@msd.com

Study contact

ClinicalTrialsDisclosure@msd.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/07/2024

Actual: 22/07/2024

Study start date

Planned: 04/01/2026

Actual: 12/01/2026

Data analysis start date

Planned: 31/12/2027

Date of final study report

Planned: 15/11/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

MK-3475-G18-00-v3-Protocol_final-redaction.pdf (398.56 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This retrospective cohort study will be conducted using the Flatiron Health US-based deidentified electronic health record databases to characterize the real-world effectiveness of pembrolizumab for the treatment of non-small cell lung cancer (NSCLC) across races, ethnicities, and age groups.

Main study objective:

The main objective of this study is to evaluate the real-world effectiveness of pembrolizumab monotherapy and pembrolizumab in combination with platinum-based chemotherapy (PBC) in United States (US)-based NSCLC patients by estimating real-world overall survival (rwOS) among the following subgroups: Race (racial minorities [e.g., Black or African American, Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and Other Race] and white patients), Hispanic/Latino ethnicity (Hispanic/Latino patients and not Hispanic/Latino patients), and Age (elderly patients ≥75 years and younger patients <75 years).

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

(L01FF02) pembrolizumab

pembrolizumab

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Adult patients diagnosed with non-small cell lung cancer (NSCLC) and treated with pembrolizumab (monotherapy or in combination with platinum-based chemotherapy [PBC]) between the eligibility October 2, 2015 and June 30, 2025 in the US will be eligible for inclusion in this study.

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

10.000

Study design details

Setting

This retrospective cohort study will be conducted using the Flatiron Health US-based deidentified electronic health record (EHR)-derived databases: early non-small cell lung cancer (eNSCLC) Flatiron Health Research Database (FHRD), and advanced non-small cell lung cancer (aNSCLC) FHRD.

The study will include adult patients diagnosed with NSCLC and treated with pembrolizumab (monotherapy or in combination with PBC) between October 2, 2015 and June 30, 2025.

Outcomes

The primary outcome of interest for the current study will be death, as measured by rwOS, defined as the time from pembrolizumab treatment start to date of death.

Patients without a date of death will be censored on the date of the last follow-up or data cutoff date, whichever occurs first.

Data analysis plan

Real-world overall survival will be estimated using Kaplan-Meier methods for each of the following subgroups: race (racial minorities, white), ethnicity (Hispanic/Latino, not Hispanic/Latino), and age group (elderly, younger). Median survival times and the probabilities of survival at key milestones of interest (e.g., 1-year, 2-year) and corresponding 95% confidence intervals will

be calculated.

These methods will be used to describe estimates of real-world overall survival for each subgroup.

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 data source

Data source(s), other

Flatiron Health: early non-small cell lung cancer (eNSCLC) Flatiron Health Research Database (FHRD), and advanced non-small cell lung cancer (aNSCLC) FHRD.

Data sources (types)

Electronic healthcare records (EHR)

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