Real-World Treatment Patterns and Clinical Outcomes of BRAF V600-Mutant Metastatic Melanoma Patients Treated at Academic Oncology Centers in the United States

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Last updated: 30/03/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000307

Study ID

1000000307

DARWIN EU® study

No

Study countries

United States

Study description

The overarching aim of this study is to describe the real-world characteristics, treatment patterns, and clinical outcomes of patients with BRAF V600-mutant MM presenting for care at academic oncology centers in the US from January 1, 2018 to June 30, 2024 (or the most recent date of data availability.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kristina Chen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 04/04/2023

Study start date
Planned: 01/10/2025

Data analysis start date
Planned: 30/01/2026

Date of final study report
Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

C4221039_RW Treatment Patterns and Clinical Outcomes in BRAF+ MM_Study Protocol_V1.0_17Oct2024_REDACTED.pdf (1.72 MB)

C4221039_Treatment Patterns and Clinical Outcomes in BRAF+ MM_Non Interventional Study Protocol_v2.0_29AUG2025_Redacted.pdf (3.18 MB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A non-interventional (NI) longitudinal cohort design will be employed for this study.
Deidentified patient data collected retrospectively from academic oncology centers will be used to address all study objectives.

Main study objective:
8.1. Primary Objectives
1. Describe the real-world treatment patterns (i.e., MM treatments, treatment interruptions, reasons for treatment interruptions, treatment discontinuations, reasons for treatment discontinuations, treatment switch, time to treatment discontinuation[TTD], time to treatment switch [TTS], time to next treatment or death [TTNTD]) of
patients with BRAF V600-mutant MM, overall and for specific treatment regimens, classes, or sequences (as determined with clinical input)
2. Describe the baseline demographic and clinical characteristics of patients with BRAF V600-mutant MM, overall and for specific treatment regimens, classes, or sequences

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name
BRAFTOVI
MEKTOVI

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

ENCORAFENIB

BINIMETINIB

Anatomical Therapeutic Chemical (ATC) code

(L01EC03) encorafenib

encorafenib

(L01EE03) binimetinib

binimetinib

Medical condition to be studied

Metastatic malignant melanoma

Population studied

Short description of the study population

BRAF V600 Mutant Metastatic Melanoma Patients

Age groups

- **Adult and elderly population (≥18 years)**

Study design details

Setting

This study will be conducted in patients with BRAF V600-mutant MM receiving treatment with SOC regimens of interest at academic oncology centers contributing to the [Redacted] from January 1, 2018 to June 30, 2024 (or most recent date of data availability).

Outcomes

Outcomes includetreatment patterns(i.e., treatment regimens, number of LOTs received, treatment interruptions, reasons for treatment interruptions, treatment switch, TTS, TTNTD, treatment discontinuation, TTD, reasons for treatment discontinuation, treatment sequences), and clinical outcomes (i.e., PFS, and OS).

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)

Electronic healthcare records (EHR)

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