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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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000307

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: 18/11/2024

Data analysis start date

Planned: 06/12/2024

Date of final study report

Planned: 20/06/2025

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)

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

Study type:

Non-interventional study

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.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

Adult and elderly population (≥18 years)

Data management

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