

# Retrospective analysis of safety in elderly metastatic or unresectable BRAF V600 melanoma patients treated with Tafinlar (dabrafenib) plus Mekinist (trametinib) and correlation with clinical features and non-elderly patients

**First published:** 08/03/2019

**Last updated:** 02/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS28059

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### Study ID

36726

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### DARWIN EU® study

No

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### Study countries

## Study description

The purpose of this study is to define the real-world care of elderly metastatic or unresectable BRAF V600 melanoma patients treated with dabrafenib and trametinib in Spain, and provide more data regarding safety in this population. The secondary endpoints will also analyze potential confounding factors, as well as exploratory differences on efficacy. This is a non-interventional, national and purely retrospective study based on secondary use of data from individual medical records to evaluate the safety and real-world management of dabrafenib or combination with trametinib in elderly and non-elderly patients with metastatic or unresectable BRAF V600 melanoma. The study includes a selection period of 7 months and a single visit aimed at obtaining the informed consent of patients (when the patient is alive), which will coincide with one of those regularly conducted by patients over their routine follow-up, without interfering with the investigator' clinical practice.

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## Study status

Finalised

## Research institutions and networks

### Institutions

**Novartis Pharmaceuticals**

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## Institution

Hospital Universitario de Torrecardenas Almeria,  
Hospital Virgen de la Salud, Toledo Toledo,  
Hospital Nuestra Señora de la Candelaria Santa  
Cruz de Teneirife, ICO Badalona (Hospital  
Germans Trias i Pujol) Badalona (Barcelona),  
Hospital de la Santa Creu i Sant Pau Barcelona,  
Hospital Universitario Central de Asturias Oviedo,  
Onkologikoa San Sebastian, Hospital Universitario  
Marqués de Valdecilla Santander, Hospital Clínico  
de Valencia Valencia, Hospital Clínico San Carlos  
Madrid

## Contact details

### **Study institution contact**

Novartis Clinical Disclosure Officer

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Study contact

**Primary lead investigator**

Novartis Clinical Disclosure Officer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 22/11/2019

Actual: 22/11/2018

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**Study start date**

Planned: 01/03/2019

Actual: 26/03/2019

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**Data analysis start date**

Planned: 15/10/2019

Actual: 09/01/2020

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**Date of final study report**

Planned: 01/09/2020

Actual: 17/07/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Farmaceutica, S.A

## Study protocol

[CDRB436BES04\\_11Jan2019\\_FINAL\\_Redacted.pdf](#) (598.06 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Other study registration identification numbers and links

CDRB436BES04,NOV-DAB-2019-1

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of the study is to describe safety and real-world management of abrafenib and trametinib in the elderly (? 75 years old) Spanish population.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

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

DABRAFENIB

TRAMETINIB

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### **Medical condition to be studied**

Malignant melanoma

## Population studied

### **Short description of the study population**

The study population have been adult patients with metastatic or unresectable BRAF V600 melanoma, who have received at least one dose of dabrafenib combined with trametinib or dabrafenib monotherapy (in case that combination treatment was available and monotherapy was considered a medical decision).

Criteria for inclusion: Patients will be included in the study if all of the following criteria are met:

1. Age  $\geq$  18 years old
2. Stage IIIC unresectable or stage IV melanoma with BRAF V600 mutation
3. Treatment with at least one dose of dabrafenib plus trametinib, or with dabrafenib monotherapy due to clinician decision (safety, contraindications, etc.) at one of the participating study sites. Patients treated in a compassionate use program are eligible following local regulation.
4. Written informed consent following local regulation (if the patient is alive). If the effort to obtain the informed consent is beyond that is reasonable and feasible, then Ethics Independent Committees (EICs) approval must be obtained (as established in local the regulation Orden SAS 3470/2009).
5. Available medical records

Criteria for exclusion: Patients are excluded from participating in this study if one or more of the following criteria are met:

1. Patients treated with dabrafenib monotherapy before trametinib was

available (June 2013).

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### **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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Malignant melanoma patients

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### **Estimated number of subjects**

205

## **Study design details**

### **Outcomes**

Safety measures and endpoints are as follows, and should be provided in the analysis for patients <75 y.o. and ≥ 75 y.o. (primary endpoint) separately:- occurrence and intensity (grade CTC-AE v4.03) of adverse events- dose delays, dose adjustments, or treatment discontinuation for the management of adverse events. Secondary efficacy measures and endpoints should be provided in the analysis for patients <75 y.o. and ≥ 75 y.o.:-Response rate by RECIST (v1.1)- Progression-free survival-Overall survivalDemographics/clinical characteristics: age, sex, stage of disease, metastatic disease, comorbidities, concomitant

medications, ECOG and LDH. Real-world management: line of treatment, discontinuation, etc

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### **Data analysis plan**

This study is descriptive in nature and no formal hypotheses will be tested. The first step in the evaluation of the data will be to use standard exploratory and descriptive analyses to gain an understanding of the qualitative and quantitative nature of the data collected and of the characteristics of the sample studied. All data collected and endpoints will be summarized using descriptive statistics in addition to statistical modeling. Absolute and relative frequency distributions of qualitative variables will be presented, as well as mean, standard deviation, median, minimum and maximum values of quantitative ones. Ninety-five percent (95%) confidence intervals (CI) will be presented for the main quantitative variables. When an inferential analysis is required, parametric tests will be used for continuous variables and nonparametric tests in the case of ordinal or categorical or nonparametric variables. All hypothesis tests will be two-sided and with a significance level of 0.05.

## Documents

### **Study results**

[CDRB436BES04\\_CSR FINAL V17Jul2020\\_Redacted.pdf](#) (1.83 MB)

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## 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

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### Data sources (types), other

For all variables of interest, data sources will be the patients' medical records.

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No