

# A NON-INTERVENTIONAL STUDY TO INVESTIGATE THE EFFECTIVENESS, SAFETY AND UTILIZATION OF COBIMETINIB AND VEMURAFENIB IN PATIENTS WITH AND WITHOUT BRAIN METASTASIS WITH BRAF V600 MUTANT MELANOMA UNDER REAL WORLD CONDITIONS (coveNIS)

**First published:** 10/04/2017

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS18539

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### Study ID

47801

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### DARWIN EU® study

No

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## Study countries

Germany

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## Study description

This prospective multi-center non-interventional study will include patients with an underlying diagnosis of BRAF V600 mutated unresectable or metastatic malignant melanoma, either with or without cerebral metastases. Data collection during therapy with Cobimetinib / Vemurafenib should reflect clinical routine. Study duration will be three years. Data from individual patients will be documented up to three years.

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## Study status

Finalised

## Contact details

### Study institution contact

Medical Information Medical Information  
grenzach.medical\_information@roche.com

Study contact

[grenzach.medical\\_information@roche.com](mailto:grenzach.medical_information@roche.com)

### Primary lead investigator

Carolin Bender

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 28/02/2017

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**Study start date**

Planned: 30/06/2017

Actual: 21/06/2017

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**Date of final study report**

Planned: 30/04/2022

Actual: 21/04/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Roche

## Study protocol

[ML39302\\_Protocol\\_Redacted.pdf](#) (357.12 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)?**

EU RMP category 3 (required)

# Other study registration identification numbers and links

ML39302

## 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:**

Assessment of risk minimisation measure implementation or effectiveness  
Drug utilisation  
Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective for this study is as follows: To estimate OS according to cohorts with cerebral and without cerebral metastases

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

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

COBIMETINIB

VEMURAFENIB

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### **Additional medical condition(s)**

unresectable and metastatic melanoma with a BRAF V600 mutation

## Population studied

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

Patients receiving treatment for BRAF V600-mutated unresectable or metastatic mM with a combination of vemurafenib and cobimetinib according to standard of care and in line with the current summary of product characteristics (SmPC)/local labeling and who have no contraindication to a treatment with a combination of vemurafenib and cobimetinib therapy as per the local label are eligible for observation in this non interventional study if the following criteria applies.

Patients must meet the following criteria for study entry:

- Adult patients with unresectable or metastatic melanoma with a BRAF 1/600 mutation according to SmPC
- Be willing and able to provide informed consent for the non-interventional study.
- Male or female patient being 2 18 years of age on day of signing informed

consent.

- Histologically confirmed diagnosis of unresectable or metastatic mM (according to the cobimetinib label)
- Presence of BRAF mutation (V600) in tumor tissue prior to enrolment.

Patients who meet any of the following criteria will be excluded from study entry:

- Previous treatment with BRAF- and/or MEK inhibitors prior to study entry
  - Hypersensitivity to the active substances or to any of the excipients
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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**

Multiple Myeloma patients

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### **Estimated number of subjects**

225

## Study design details

### **Outcomes**

Primary Variable The primary outcome measure for this study is Overall Survival (OS), Secondary Variables: Progression free survival (PFS), Objective response rates (ORR), Time to CNS relapse/development of cerebral metastases, Description of previous therapies and therapies after cobimetinib/ vemurafenib discontinuation, Description of Radiotherapy, Description of Concomitant medication, Quality of life (QoL)

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### **Data analysis plan**

All effectiveness and safety variables documented in this study will be analyzed by means of descriptive analyses. Continuous data will be summarized using mean, standard deviation, median, minimum and maximum. Categorical variables will be expressed as absolute and relative number and 95% CI. Kaplan-Meier estimates and Cox-regression will be used to model data on time to disease progression and OS.

## Documents

### **Study results**

[Final CSR Synopsis, Study ML39302 \(coveNIS\)\\_Redacted.pdf](#) (1.96 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**

Prospective patient-based data collection

## **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