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

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Study Finalised

Administrative details

EU PAS number

EUPAS18539

Study ID

47801

DARWIN EU® study

No

Study countries

Germany

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.

Study status

Finalised

Contact details

Study institution contact

Medical Information Medical Information
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Study contact

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

Study start date
Planned: 30/06/2017

Actual: 21/06/2017

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

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

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

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

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)

Special population of interest

Other

Special population of interest, other

Multiple Myeloma patients

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)

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)

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No