

# ZeSS: A Prospective Observational Safety Study of Patients with BRAFV600 Mutation-positive Unresectable or Metastatic Melanoma Treated with Vemurafenib (Zelboraf®)

**First published:** 21/12/2012

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS3125

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### Study ID

21125

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### DARWIN EU® study

No

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### Study countries

☐ Austria

☐ Belgium

- ☐ Czechia
  - ☐ Germany
  - ☐ Ireland
  - ☐ Italy
  - ☐ Netherlands
  - ☐ Poland
  - ☐ Sweden
  - ☐ United Kingdom
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### **Study description**

This multi-center, prospective, observational safety study will evaluate the safety and effectiveness of Zelboraf (vemurafenib) in a real world setting. Data from Zelboraf-treated patients with BRAF-V600 mutation-positive unresectable or metastatic melanoma will be collected for 2 years.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

N/A

Multiple centres: 100 centres are involved in the study

## Contact details

### Study institution contact

Natalia Sadetsky [global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

Study contact

[global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

### Primary lead investigator

Natalia Sadetsky

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 27/04/2012

Actual: 27/04/2012

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### Study start date

Planned: 25/03/2013

Actual: 22/03/2013

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### Date of final study report

Planned: 31/03/2017

Actual: 21/03/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

F. Hoffmann-La Roche

## Regulatory

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

Yes

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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

GP28492

## 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

**Data collection methods:**

Primary data collection

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**Main study objective:**

This study will be a real-world evaluation of the effectiveness of the Summary of Product Characteristics (SmPC) monitoring recommendations for the safety of vemurafenib.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Safety registry

## Study drug and medical condition

**Name of medicine**

ZELBORAF

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**Medical condition to be studied**

Malignant melanoma

## Population studied

## Short description of the study population

Consenting patients identified within one month of initiating treatment with vemurafenib were enrolled from 85 clinical practice sites.

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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

300

## Study design details

### Outcomes

Incidence of cutaneous squamous cell carcinoma  
Incidence of non-cutaneous squamous cell carcinoma  
Incidence of QT prolongation (defined as QTc >500 ms or an increase in QTc >60 ms)  
Incidence of abnormal liver function, Incidence of a second (or subsequent) primary melanoma  
Incidence of gastrointestinal polyps

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## Data analysis plan

Since the purpose of this Study is largely descriptive, there are no formal sample size calculations based on formal comparative hypothesis testing. Most statistical analyses will be descriptive. Descriptive statistics include number of subjects, means, standard deviations, medians, minima, and maxima for continuous variables (e.g. age and duration of treatment) and frequencies and percentages for categorical variables (e.g. gender and event types). Two sided 95% confidence intervals will be estimated as appropriate. Exposition to the study drug will be summarised and listed with respect to treatment duration, average daily dose, total dose, frequency and reason for dose reductions, time to first dose reduction and reasons for discontinuation from the study drug.

## Documents

### Study results

[GP28492\\_CSR\\_Abstract\\_Redacted.pdf](#) (725.79 KB)

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## Data management

## 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**

Unknown