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

Study ID

21125

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium

- [ ] Czechia
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Sweden
- [ ] United Kingdom

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.

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

Study contact

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

Study start date

Planned: 25/03/2013

Actual: 22/03/2013

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

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

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

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Safety registry

Study drug and medical condition

Name of medicine

ZELBORAF

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.

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

Malignant melanoma patients

Estimated number of subjects

300

Study design details

Outcomes

Incidence of cutaneous squamous cell carcinomaIncidence of non-cutaneous squamous cell carcinomaIncidence 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 sizecalculations 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 andevent 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)

Data management

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

Unknown