Prospective Observational Cohort Study to Describe the Use of Vectibix® in Combination With Chemotherapy in Routine Clinical Practice for Patients With Wild-type KRAS Metastatic Colorectal Cancer (20120100)

First published: 30/11/2012

Last updated: 31/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20948

EU PAS number

EUPAS3180

Study ID

20948

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

Study description

This is a multicenter, observational prospective cohort study in France and Germany. Treatment centres with a focus on treating subjects with mCRC will be prospectively defined for potential inclusion in the study. Eligible subjects will be enrolled and have retrospective data collected from Baseline up to the point of enrolment. All subsequent chemotherapy cycles and Vectibix® doses will be recorded prospectively. Each subject will have data collected until approximately 30 days after the end of Vectibix® treatment, death, withdrawal of consent, loss to follow-up or up to 12 months from the first dose of Vectibix®, whichever occurs first.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- ☐ United States

First published: 01/02/2024

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Institution

Vitanus GmbH Germany, Vinzenz von Paul Kliniken gGmbH Marienhospital Stuttgart Germany, Gemeinschaftspraxis Dr. Maintz, Groschek Hinske Germany, Onkologische Gemeinschaftspraxis Germany, Schwerpunktpraxis Hamatologie Onkologie Germany, Zentrum fur Onkologie und Urologie Rostock Germany, Onkologisches Zentrum Drs. Bauer and Kremers Germany, Dres. Kailhori/Langer/Nusch Germany, Schwerpunktpraxis Hamatologie und Onkologie German, Universitatsklinikum Magdeburg Germany

Contact details

Study institution contact
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Primary lead investigator

Glodal Development Leader Amgen, Inc

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/06/2012

Study start date

Planned: 10/12/2012

Actual: 10/12/2012

Data analysis start date

Planned: 21/04/2017

Actual: 12/04/2017

Date of final study report

Planned: 28/08/2017

Actual: 28/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Vectibix_20120100_Protocol_113012.pdf(569.55 KB)

20120100 Protocol Amend 4 2015-04-09 English_2.pdf(754.68 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

Treatment patterns of Vectibix® and concomitant chemotherapy for mCRC (12mo)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

Subjects with wild-type RAS metastatic colorectal cancer CRC treated with Vectibix® according to the SmPC in France and Germany.

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

Colorectal cancer patients

Estimated number of subjects

740

Study design details

Outcomes

Treatment patterns of Vectibix® and concomitant chemotherapy for mCRC (12mo), Healthcare resource utilization (12mo)Demography of disease population (12mo)Response to Vectibix® (12mo)Planned anti-cancer treatment initiated post Vectibix (12 mo)

Data analysis plan

The analysis of this study will be descriptive in nature. The data will be summarized for patients with metastatic colorectal cancer (mCRC) with tumour expressing wild type (non-mutated) KRAS who received Vectibix® in combination with FOLFOX as first-line treatment and subjects who received Vectibix® in combination with FOLFIRI as second line treatment and received

first-line fluoropyrimidine-based chemotherapy (excluding irinotecan). The data will be summarized by country to fulfil local post reimbursement requirements. For continuous outcomes, the mean, standard deviation, median, and range will be provided. For categorical variables, the frequency and percentage, with two-sided 95% CI, will be displayed for the treatment pattern of Vectibix®. Summary tables and analyses will be based on FLFAS and SLFAS and corresponding local tumour response analysis sets. Summary statistics will be reported for the significant covariates.Selected sensitivity analyses may be performed.

Documents

Study results

CICERO_ORSR_abstract_20170816 (002).pdf(112.78 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective data will be collected to verify eligibility up to Baseline (baseline equals the first dose of Vectibix®). All subsequent chemotherapy cycles and Vectibix® doses will be recorded prospectively.

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