RECORA- Regorafenib in patients with metastatic colorectal cancer (mCRC) after failure of standard therapy

First published: 08/10/2013

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4934

Study ID

23329

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The purpose of the study is to investigate the safety and effectiveness of Stivarga in patients with metastatic colorectal carcinoma in routine use in Germany. The study is purely observational, only data from routine treatment are to be collected. The treatment and treatment conditions are solely at discretion of the treating physician.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

Study contact

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Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/07/2013

Study start date

Planned: 15/10/2013

Actual: 31/10/2013

Date of final study report

Planned: 31/03/2018

Actual: 09/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

SV1313_CSP_2013-07-22_signed.pdf(859.97 KB)

16665_SV1313_CSP_3.0_2016-04-06_signed.pdf(2.35 MB)

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

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of this study is the comparison of two cohorts of hepatocellular carcinoma patients regarding overall survival (OS) from time of TACE non-eligibility. The two cohorts of special interest are defined based on the investigators' treatment decisions (i.e. patients with early start of Sorafenib treatment vs. patients without early start of Sorafenib treatment).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

NEXAVAR

Anatomical Therapeutic Chemical (ATC) code

(L01XE21) regorafenib

regorafenib

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

Patients with metastatic colorectal carcinoma for whom the decision has been taken by the investigator to treat with Stivarga® as 3rd or 4th line treatment.

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

500

Study design details

Outcomes

Overall survival, Progression-free survivalTime to progressionDisease control rate (DCR)Duration of Stivarga treatmentTumor status at different visitsIncidence of treatment emergent adverse events (TEAE)

Data analysis plan

In general, statistical analyses will be of explorative and descriptive nature. Analyses will be performed for the total study population (overall analysis) and

separately for the two patient cohorts of special interest, as appropriate. The primary efficacy endpoint is Overall Survival (OS). It is defined in this study as the time period from documented TACE non-eligibility to death due to any cause. For the two cohorts of special interest, Kaplan-Meier (KM) estimates for OS will be displayed. Furthermore, these two cohorts will be compared regarding overall survival using a Cox proportional hazards model. Where applicable, the propensity score approach will be applied in order to compare the two cohorts.

Documents

Study results

16665_EU-PAS_Abstract.pdf(63.82 KB)

Study report

SV1313_16665_RECORA_OS report_EU PAS Register.pdf(1.67 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

Unknown