

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

First published: 08/10/2013

Last updated: 23/04/2024

Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/23329>

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 institution and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated
01/02/2024

Institution

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG

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 and secondary data collection

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

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

Nexavar

Anatomical Therapeutic Chemical (ATC) code

100000144785

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 survival, Time to progression, Disease control rate (DCR), Duration of Stivarga treatment, Tumor status at different visits, Incidence 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

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