Safety and Effectiveness of Ramucirumab in Patients with Advanced Gastric Cancer in the European Union and North America: A Prospective Observational Registry (I4T-MC-JVDD)

First published: 30/11/2015

Last updated: 19/04/2022

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46805

EU PAS number

EUPAS9400

Study ID

46805

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] Switzerland
- [ ] United States

Study description

This is a prospective, non-interventional, non-comparative, observational cohort study / registry in the EU and North America. The overall study objective is to evaluate the safety and effectiveness of ramucirumab administered as monotherapy or in combination therapy for second-line treatment of adult patients with advanced gastric cancer under real-world disease conditions.

Study status

Finalised

Research institutions and networks

Institutions

Quintiles

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Yu-Jing Huang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/02/2015

Actual: 24/02/2015

Study start date

Planned: 15/12/2015

Actual: 09/12/2015

Date of interim report, if expected

Actual: 24/05/2019

Date of final study report

Planned: 15/12/2021

Actual: 10/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

RAM JVDD PASS (v2.0).pdf(537.58 KB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The overall study objective is to evaluate the safety and effectiveness of ramucirumab under real-world disease conditions in the Europe and North America

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RAMUCIRUMAB

Medical condition to be studied

Gastric cancer stage IV

Population studied

Short description of the study population

This study will include a cohort of approximately 600 adult patients from the EU and North America with advanced gastric cancer or GEJ adenocarcinoma whose disease has progressed after prior chemotherapy and who are treated with ramucirumab alone or in combination therapy as second-line therapy under real-world disease conditions. The decision to initiate use of ramucirumab is made independently by the participant and their health care provider and is not mandated by the study design or protocol.

Inclusion Criteria

[1] Adult patients (age ≥ 18 years at enrolment) with advanced gastric cancer or GEJ adenocarcinoma whose disease has progressed after prior chemotherapy.

[2] Patients who initiate ramucirumab treatment either as a single agent or in combination with chemotherapy.

[3] Patients who have been fully informed and have given written consent to the use of the needed information to be part of the observational study.

Exclusion Criteria

[4] Patients who have received more than 1 line of chemotherapy for advanced gastric cancer or GEJ adenocarcinoma.

[5] Patients concurrently participating in any study including administration of any investigational drug (including ramucirumab) or procedure (including survival follow-up).

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

Renal impaired

Hepatic impaired

Estimated number of subjects

600

Study design details

Outcomes

To describe the safety of ramucirumab administered as monotherapy or in combination therapy for second-line treatment of adult patients with advanced gastric cancer under real-world disease conditions in the Europe and North America, To describe the safety profile in the following subgroups: Elderly patients, patients with cardiac comorbidities, hepatic impairment, and renal impairment. To describe the effectiveness of ramucirumab administered as monotherapy or in combination therapy for second-line treatment of adult patients with advanced gastric cancer under real-world disease conditions in the Europe and North America

Data analysis plan

This population includes all patients who have given informed consent and received at least 1 dose of ramucirumab alone or in combination therapy as second-line therapy. Adverse events will be collected, coded, and categorized using the Medical Dictionary for Regulatory Activities (MedDRA). For the primary objective (that is safety), a descriptive analysis will be conducted to evaluate the safety of ramucirumab. Categorical measures will be summarised as counts

and percentages, while continuous measures will be summarised using mean, median, standard deviation, and range. For effectiveness outcomes, overall survival and progression-free survival, Kaplan-Meier estimates (including curves) will be generated. The median and survival rates at given time points (eg, 3, 6, 9, 12 months) will be computed together with their 95% CIs using the Kaplan-Meier method. Best tumour response, treatment patterns, healthcare resource utilisation, and supportive care will be summarised descriptively

Documents

Study results

I4T-MC-JVDD PASS Final Study Report_Redacted.pdf(5.37 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

No