A Prospective Post-Marketing Observational Safety Study of Cyramza® (Ramucirumab) in Patients with Gastric or Gastroesophageal Junction Adenocarcinoma in China (I4T-MC-B012)

First published: 13/06/2022

Last updated: 15/04/2024

Study | Planned

Administrative details

EU PAS number

EUPAS47676

Study ID

47677

DARWIN EU® study

No

Study countries

☐ China

Study status

Planned

Research institutions and networks

Institutions

Harbin Medical University Cancer Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Zhen-Xin Zhu zhu_zhen_xin@lilly.com

Study contact

zhu_zhen_xin@lilly.com

Primary lead investigator

Yan-Qiao Zhang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2022

Study start date
Planned: 31/12/2022

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

To describe the safety and effectiveness of Cyramza in adult patients with gastric or gastroesophageal junction adenocarcinoma.

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

Population studied

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)

Estimated number of subjects

854

Study design details

Outcomes

To describe the safety profile of Cyramza administered for treatment of adult patients with gastric or GEJ adenocarcinoma under real-world disease conditions in China. To describe the effectiveness of Cyramza administered for treatment of adult patients with gastric or GEJ adenocarcinoma under real-world disease conditions in China.

Data analysis plan

A descriptive analysis will be conducted to describe the safety and effectiveness of Cyramza. Regardless of the relatedness to Cyramza, the incidence of AEs and SAEs will be summarized. PFS and OS will be summarized as median with their 95% CIs using the Kaplan-Meier method. ORR and DCR will be summarized as percentages and 95% CI.

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)

Disease registry

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