Real-world Comparative Effectiveness of Anti-EGFRs with Doublet Chemotherapy Versus Doublet Chemotherapy with or without Bevacizumab in Firstline Among RAS/RAF Wild-type, non-dMMR/MSI High mCRC Patients with Left-sided Primary Tumors in the Flatiron Health CRC Enhanced Datamart (20240215)

First published: 21/02/2025

Last updated: 12/03/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000470

Study ID

1000000470

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/11/2024

Study start date

Planned: 29/01/2025

Actual: 29/01/2025

Data analysis start date

Planned: 03/03/2025

Actual: 03/03/2025

Date of final study report

Planned: 01/12/2025

Sources of funding

- Pharmaceutical company and other private sector

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Retrospective, active comparator, new user cohort study.

Main study objective:

The main study objectives are:

- To compare overall survival in Rat sarcoma (RAS)/ Rapidly accelerated fibrosarcoma (RAF) Wild-type (WT), non-Mismatch repair deficient (dMMR)/ Microsatellite instability (MSI) high mCRC patients with left-sided primary

tumors initiating treatment with panitumumab in combination with FOLFOX versus bevacizumab in combination with FOLFOX in the front-line (1L) setting, within the US Flatiron Health Enhanced Datamart (FH EDM).
- To compare overall survival in RAS/RAF WT, non-dMMR/MSI high mCRC patients with left-sided primary tumors initiating treatment with panitumumab in combination with FOLFOX versus FOLFOX alone in the front-line setting, within the US FH EDM.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

VECTIBIX

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

PANITUMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FE02) panitumumab

panitumumab

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

Adults with diagnosis of metastatic (Stage IV) mCRC

Age groups

Adults (18 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

22000

Study design details

Comparators

FOLFOX (Leucovorin, fluorouracil, oxaliplatin)

Bevacizumab

FOLFIRI (Leucovorin, fluorouracil, irinotecan)

CAPEOX (Capecitabine and oxaliplatin)

Outcomes

Overall Survival (OS)

Data analysis plan

The study will use propensity score weighting (inverse probability of treatment weights – IPTW) to create treatment cohorts for evaluation of the comparative effectiveness (i.e. OS) of:

1) panitumumab plus FOLFOX versus FOLFOX with or without bevacizumab in the 1L setting (primary objective); and

2) anti-epidermal growth factor receptor (EGFR) agent (panitumumab/cetuximab) versus doublet chemotherapy (FOLFOX/FOLFIRI/CAPEOX) with or without bevacizumab in the 1L setting (secondary objective).

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction