Prospective international observational cohort non-comparative study describing the safety and effectiveness of ZALTRAP® administered in combination with FOLFIRI for the treatment of patients with metastatic colorectal cancer in current clinical practice: A Post-Authorisation Safety Study (PASS) (OZONE)

First published: 03/10/2013

Last updated: 19/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4836

Study ID

34370

DARWIN EU® study

No

Study countries

- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Puerto Rico
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

This is an observational study designed to follow patients with metastatic CRC who are receiving Zaltrap in combination with FOLFIRI.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Trial Transparency Team Contact-US@Sanofi.com

Study contact

Contact-US@Sanofi.com

Primary lead investigator

Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/04/2013

Actual: 12/04/2013

Study start date

Planned: 08/10/2013

Actual: 08/10/2013

Date of final study report

Planned: 11/08/2018

Actual: 04/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANOFI

Study protocol

obs13597-16-1-1-protocol-20130701.pdf (480.06 KB)

obs13597-amended-protocol02.pdf (623.21 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To describe the long term safety & clinical outcomes of ZALTRAP® in combination with FOLFIRI in patients treated in daily practice for a mCRC after failure of an oxaliplatin-based regimen.

To assess safety of ZALTRAP® in the following cohorts: Elderly patients (?65 years old); Patients with renal or hepatic impairment; Non Caucasian; Number and type of prior anti cancer-therapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ZALTRAP

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

AFLIBERCEPT

Anatomical Therapeutic Chemical (ATC) code

(L01XX44) aflibercept

aflibercept

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

Patients treated with ZALTRAP® in the clinical setting (not as part of an interventional clinical trial) and followed for 24 months after initiation of ZALTRAP®.

Patients with following criteria were included:

1. Patient planned to be treated with ZALTRAP® in combination with a 5FU plus irinotecan regimen (FOLFIRI) for mCRC after failure of an oxaliplatin based regimen (including bevacizumab pretreated patients). Patient for which the Physician has decided to prescribe ZALTRAP® independently from entry in study
2. Age ≥18 years old
3. Availability of a written informed consent

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

Hepatic impaired

Renal impaired

Estimated number of subjects

750

Study design details

Outcomes

Safety: TEAEs

Efficacy: OS, physician assessed PFS and RR, Effectiveness in the following cohorts:
• Elderly (≥65 years),
• Hepatic or renal impairment patients,
• Non Caucasian,
• Number and type of prior anti-cancer therapy (e.g. prior bevacizumab)

Health Resource Utilization

Data analysis plan

All statistical analyses will be descriptive. Safety endpoints will be summarized as count and frequencies with 95% confidence interval. Best Overall Response will be summarized as count of patients and frequencies with 95% CI. For the

PFS and OS outcomes, the Kaplan-Meier estimates will be computed and the 95% confidence interval for the median survival times / survival rates at given time points will be provided. Subgroups analyses will be performed in following patients cohorts: elderly, hepatic or renal impairment, non-Caucasian and number & type of prior anti-cancer therapy.

Documents

Study results

obs13597-body.pdf (1.2 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

No