Drug Utilization Study of ZALTRAP® (aflibercept) Using European Databases (Zaltrap Utilization Study)

First published: 05/12/2013

Last updated: 25/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5365

Study ID

16787

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Spain

United Kingdom

Study description

During the registration application with EMA for aflibercept to be marketed in the EU, Sanofi proposed a three-year drug utlization study (DUS) using European databases as part of the post-approval commitments. The primary objectives of the proposed DUS are to monitor ZALTRAP use in cancer patients including potential off-label use and evaluate the potential for intravitreal use.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

Vernon Schabert VSchabert@us.imshealth.com

Study contact

VSchabert@us.imshealth.com

Primary lead investigator

Vernon Schabert

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/08/2013

Actual: 16/10/2013

Study start date

Planned: 01/01/2013

Actual: 01/01/2013

Data analysis start date

Planned: 02/06/2014

Actual: 02/06/2014

Date of interim report, if expected

Planned: 30/11/2014

Actual: 30/11/2014

Date of final study report

Planned: 30/11/2016

Actual: 30/11/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

Zaltrap DUS Protocol Final_revision.pdf(330.09 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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

- To evaluate the frequency distribution of cancer type(s) among patients who receive treatment containing ZALTRAP in the five largest national markets in Europe (EU5): United Kingdom (UK), France, Germany, Italy, and Spain.
- To describe different treatment combinations among patients who receive therapy containing ZALTRAP in the EU5.
- To evaluate the proportion of ZALTRAP patients with observed intravitreal use in England.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

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 neoplasm

Colorectal cancer metastatic

Population studied

Short description of the study population

Patients from the EU5 for whom the physician reported the receipt of at least one dose of ZALTRAP, as a current therapy.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

100

Study design details

Data analysis plan

Descriptive statistics will be provided

Documents

Study results

Zaltrap DUS Study Final Report.pdf(305.12 KB)

Data management

Data sources

Data source(s)

HTI – Hospital Treatment Insights

Data source(s), other

IMS Oncology Analyzer, United Kingdom

Data sources (types)

Other

Data sources (types), other

The IMS Oncology Analyzer™ (OA) is a quarterly structured survey of treated prevalence for over 25 leading solid tumors and hematological malignancies.

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