Votrient liver data meta-analysis of phase II and III RCC and STS studies (200277)

First published: 03/04/2014

Last updated: 30/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18181

EU PAS number

EUPAS6242

Study ID

18181

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/03/2013

Actual: 13/03/2013

Study start date
Planned: 07/04/2013

Actual: 07/04/2013

Date of final study report
Planned: 23/05/2013

Actual: 23/05/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

200277-meta-analysis-plan-redact.pdf(157.39 KB)

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:

Other

If ‘other’, further details on the scope of the study

Meta-analysis

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of these analyses will be to characterise the liver safety profile of pazopanib in subjects with locally recurrent and/or metastatic renal cell carcinoma or advanced or recurrent soft tissue sarcoma.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

PAZOPANIB

Population studied

Short description of the study population

Meta-analysis of 1500 pazopanib treated patients from phase II and III trials.

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

Estimated number of subjects

1500

Study design details

Data analysis plan

A summary of liver re-challenges, adaptations and recovery will be provided. The re-challenge is defined as an ALT elevation, followed by treatment interruption and subsequently an ALT value of Grade 1 or below on or prior to re-starting study treatment, where the ALT elevation means ALT>3xULN during on-therapy window and ≤ 3xULN at baseline. The adaptation is defined as an ALT elevation followed by an ALT assessment returning to baseline grade or below without any dose interruption between the ALT elevation and normalisation. Recovery is defined as ALT Grade 1 or below for 2 consecutive visits or Grade 1 or below for one visit if subject discontinued and no subsequent ALT data are available.

Documents

Study results

Synop-200277.pdf(109.16 KB)

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

Unknown