Votrient Liver Data Meta-analysis (200276)

First published: 02/04/2014

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6229

Study ID

16867

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

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: 01/04/2013

Actual: 01/04/2013

Study start date

Planned: 01/04/2013

Actual: 01/04/2013

Date of final study report

Planned: 30/04/2014

Actual: 30/07/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

200276-metaanalysis-redact.pdf(329.63 KB)

Regulatory

Was the study required by a regulatory body?

No

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:

Other

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

Meta-analysis

Data collection methods:

Secondary use of data

Main study objective:

To characterize pazopanib-induced liver toxicity and to explore potential predictive and/or prognostic factors for pazopanib-induced liver events and risk factors for rechallenge failure.

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

Patients from US suffering from pazopanib-induced liver toxicity.

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

2080

Study design details

Data analysis plan

Data will be summarised by indication and also by the peak ALT level during the first ALT elevation >3xULN (>3-5xULN, >5-8xULN, >8-20xULN and >20xULN). This is defined as the peak ALT value from the initial elevation >3xULN until recovery. Recovery is defined as ALT returning to 2.5xULN or below for two consecutive tests or dropping to 2.5xULN or below once after study treatment discontinuation with no further data available. Recovery also includes those cases where dose was interrupted after an ALT>3xULN event, then ALT returned to 2.5xULN or below with only one test and subject was re-challenged before their next ALT test.

Documents

Study results

gsk-200276-clinical-study-report-redact.pdf(1.19 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

Unknown