# 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)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

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

Meta-analysis

**Data collection methods:**

Secondary use of data

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**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.

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**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)

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**Special population of interest**

Hepatic impaired

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**Estimated number of subjects**

2.080

# 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