PGx6652: Genetic Evaluation of Pazopanib –Related Hepatotoxicity (117365)

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Study   Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/16864

EU PAS number
EUPAS6189

Study ID
16864

DARWIN EU® study
No

Study countries
United Kingdom

Study status
Finalised

Research institution and networks

Institutions

GlaxoSmithKline (GSK)

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:
02/11/2012
Actual:
02/11/2012

Study start date
Planned:
16/11/2012
Actual:
16/11/2012

Date of final study report
Planned:
31/07/2014
Actual:
20/05/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

veg117365-reporting-and-analysis-plan-redact.pdf(316.43 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
Pharmacogenetics study

Data collection methods:
Secondary data collection

Main study objective:

The objective is to identify genetic markers associated with pazopanib-related hepatotoxicity

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Pharmacogenetics study

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 with pazopanib-related hepatotoxicity who were evaluated for biomarkers.

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)

Estimated number of subjects
1000

Study design details

Outcomes
Occurance of serious liver injury, maximum ALT measured within the on-therapy window, and time-to-event defined as the time from initiation of pazopanib treatment until the first on-therapy event

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Data analysis plan
For the candidate gene analysis, association between candidate gene alleles/genotypes and the case/control endpoint will be tested using the logistic regression analysis with

appropriate adjustment of covariates. For the GWAS analysis, association between the continuous form of endpoints and genetic variants across the entire genome will be tested using linear and Cox regressions.

Documents

Study results
[117365-Clinical-Study-Result-Summary.pdf](153.65 KB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Retrospective analysis of data from clinical studies

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