An Open-Label, Multi-Centre, Non-Interventional, Post-Marketing Surveillance (PMS) to Monitor the Safety and Effectiveness of Votrient Administered in Korean Patients According to the Prescribing Information (115578)

First published: 16/12/2013

Last updated: 31/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20900

EU PAS number

EUPAS5153

Study ID

20900

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

Non-Interventional, Open-Label, Single Group, Multicentric Post-Marketing Surveillance to Monitor the Safety and Effectiveness of Pazopanib Administered in Korean Patients According to the Prescribing Information

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Asan Medical Center Seoul, Korea

Contact details

Study institution contact

Clinical Disclosure Officer Clinical Disclosure Officer

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Clinical Disclosure Officer Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/01/2012

Actual: 26/01/2012

Study start date

Planned: 21/02/2012

Actual: 21/02/2012

Date of final study report

Planned: 31/12/2017

Actual: 24/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

115578 Protocol_GSK.pdf(1.05 MB)

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:

Other

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

Regulatory Post Marketing Surveillance.

Data collection methods:

Primary data collection

Main study objective:

To collect safety and effectiveness data of Votrient in Korean patients.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, open-label, single group, multicentre post-marketing surveillance.

Study drug and medical condition

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

PAZOPANIB

Population studied

Short description of the study population

Advanced renal cell carcinoma or soft tissue sarcoma patients administered Votrient at the site.

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

Immunocompromised

Renal impaired

Estimated number of subjects

3000

Study design details

Outcomes

Adverse events in patients administrated Votrient. Unexpected adverse drug reaction (ADR), serious adverse event (SAE) and effectiveness in patients administrated Votrient.

Data analysis plan

Non-interventional, open-label, single group, multicentre post-marketing surveillance.

Documents

Study results

115578.pdf(7.32 MB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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