PRINCIPAL: A prospective observational study of real world treatment patterns and treatment outcomes in patients with advanced or metastatic renal cell carcinoma receiving pazopanib (115232)

First published: 02/04/2014

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/29301

EU PAS number

EUPAS6239

Study ID

29301

DARWIN EU® study

No

Study countries

United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

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: 02/03/2012

Actual: 02/03/2012

Study start date
Planned: 23/07/2012

Actual: 23/07/2012

Data analysis start date
Planned: 03/07/2017

Actual: 30/06/2017

Date of final study report
Planned: 30/06/2018

Actual: 11/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

veg115232-protocol-redacted.pdf(787.39 KB)

veg115232-protocol-amend-redact.pdf(1.06 MB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

Prospective observational study

Data collection methods:

Primary data collection

Main study objective:

To evaluate overall survival (OS), progression-free survival (PFS) and the overall response rate (ORR) in patients treated with pazopanib

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective observational 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 advanced or metastatic renal cell carcinoma (RCC) treated for the first time with pazopanib.

Patients with following criteria were included:

1. Age 18 years or older at enrollment
2. Documented diagnosis of advanced and/or metastatic clear cell or predominantly clear cell RCC
3. Clinical decisionmade to initiate treatment with pazopanib prior to enrollment in the study, but within 30 days of enrollment

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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)

Special population of interest

Renal impaired

Estimated number of subjects

1000

Study design details

Data analysis plan

For the analysis of overall survival, the last date of known contact will be used for those patients who have not died at the time of analysis. For the analysis of progression-free survival (PFS), if the patient received subsequent anticancer therapy prior to the date of documented progression or death, progression free survival will be censored at the last adequate assessment (e.g. assessment where visit level response is complete response, partial response or stable disease) prior to the initiation of therapy. The overall response rate (ORR) will be based on the investigator assessment of overall response in the Measurable Disease (MD) population.

Documents

Study results

PZP034A2401 CSR_Redacted_PDF_A.pdf(450.76 KB)

Data management

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