Prospective non interventional study of cabozantinib tablets in adults with advanced renal cell carcinoma following prior vascular endothelial growth factor (VEGF)-targeted therapy (Cassiope)

First published: 15/12/2017

Last updated: 01/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48986

EU PAS number

EUPAS19464

Study ID

48986

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Spain
- [ ] United Kingdom

Study description

For this prospective non-interventional study, the objective is to understand the utilisation of cabozantinib in subjects with advanced Renal Cell Carcinoma following prior VEGF-targeted therapy in real life settings in terms of dose modifications due to AEs (Adverse Events) when used as a second line therapy or third and later line therapy. Other patterns of use of cabozantinib will also be described.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 103 centres are involved in the study

Contact details

Study institution contact

Medical Director

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/03/2017

Actual: 16/03/2017

Study start date
Planned: 05/01/2018

Actual: 24/04/2018

Data analysis start date
Planned: 01/09/2022

Actual: 08/09/2022

Date of interim report, if expected
Planned: 30/12/2020

Actual: 30/12/2020

Date of final study report
Planned: 31/03/2023

Actual: 19/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen Pharma

Study protocol

f-fr-60000-001-protocol.pdf(4.62 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:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To describe the pattern of dose interruptions, reductions or discontinuations of cabozantinib due to adverse events in clinical practice when used as a second

or third and later line therapy.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, international, multicentre study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XE26) cabozantinib

cabozantinib

Medical condition to be studied

Renal cell carcinoma

Population studied

Short description of the study population

Adult patients aged 18 years or older diagnosed with advanced renal cell carcinoma (RCCC) received treatment with at least one prior vascular endothelial growth factor (VEGF)-targeted therapy.

Inclusion criteria:

(1) Age ≥18 years old;

(2) Has a diagnosis of advanced RCC;

(3) Has received at least one prior VEGF-targeted therapy;

(4) For whom the treating physician has decided to start treatment with cabozantinib tablets prior to inclusion;

(5) No previous exposure to cabozantinib prior to inclusion;

(6) Not concurrently involved in an interventional study;

(7) Consents to participate in this noninterventional study.

There are no exclusion criteria for this study.

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

Other

Special population of interest, other

Patients with renal cell carcinoma

Estimated number of subjects

689

Study design details

Outcomes

Proportion of patients with dose modifications due to adverse events based on investigator’s decision (temporary interruption, dose reduction or discontinuation) when cabozantinib is used as a second line therapy, or third and later line therapy. Description of the use of cabozantinib in real-life settings, effectiveness, safety and health care resource utilization associated with management of treatment related AEs.

Data analysis plan

As this is a non-interventional study, no formal statistical testing will be performed and all the analyses will be primarily descriptive in nature. When appropriate and unless otherwise specified, 2-sided 95% confidence interval (CIs) will be displayed and if p values are presented, they will be for exploratory purposes only. The primary endpoint is the proportion of subjects with dose modifications due to AEs based on the investigator’s decision (temporary interruption, dose reduction or discontinuation). The primary analysis of the primary endpoint will be summarised descriptively for each line of treatment (second line or third and later line) and in total with their associated 2-sided 95% CIs based on the Clopper Pearson method and using the Primary Safety population.

Documents

Study results

F-FR-60000-001_CSR Abstract_Redacted (002).pdf(2.14 MB)

Study report

F-FR-60000-001_synopsis_06Nov2020.pdf(185.92 KB)

Data management

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

No