Prospective Non-interventional Study of Cabozantinib as Monotherapy or in Combination With Nivolumab in Patients With Advanced or Metastatic Renal Cell Carcinoma Under Real-life Clinical Setting in 1st Line Treatment (CABOCARE)

First published: 11/01/2024

Last updated: 13/11/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/199006

EU PAS number

EUPAS108004

Study ID

199006

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Germany

Study description

The purpose of the protocol is to describe the use of cabozantinib tablets as monotherapy or in combination with nivolumab including the number of dose reductions, dose interruptions and terminations due to (serious) adverse events in subjects with advanced or metastatic renal cell carcinoma (mRCC) treated in real-life clinical setting in 1st line treatment.

Study status

Ongoing

Research institutions and networks

Institutions

Ipsen Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 83

Contact details

Study institution contact

Director Medical

Study contact

Clinical.trials@ipsen.com

Primary lead investigator

Director Medical

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/07/2018

Study start date

Actual: 13/08/2018

Data analysis start date

Planned: 30/06/2027

Date of interim report, if expected

Planned: 30/06/2025

Date of final study report

Planned: 30/06/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IPSEN Pharma

Study protocol

A-DE-60000-009_protocol_27Nov2023_Redacted_PDFA.pdf(7.36 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Describe the use of CabometyxTM (cabozantinib) tablets as monotherapy and the use of CabometyxTM and OpdivoTM combination including the number of dose reductions, dose interruptions and terminations due to SAEs/AEs in subjects with advanced or metastatic renal cell carcinoma treated in real-life clinical setting in 1st line treatment overall and split by risk score.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective German and Austrian multicenter non-interventional study (NIS)

Study drug and medical condition

Name of medicine

CABOMETYX

OPDIVO

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

CABOZANTINIB

NIVOLUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01EX07) cabozantinib

cabozantinib

(L01FF01) nivolumab

nivolumab

Medical condition to be studied

Renal cell carcinoma

Metastatic renal cell carcinoma

Population studied

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

210

Study design details

Outcomes

- The proportion of subjects with dose reduction of cabozantinib due to Serious Adverse Events/Adverse Events (SAEs/AEs).
- The proportion of subjects with dose interruption of cabozantinib and/or nivolumab due to SAEs/AEs.
- The proportion of subjects with termination of cabozantinib /cabozantinib-nivolumab combination due to SAEs/AEs.
- Number of injection delayed of nivolumab due to SAE/AE.
- Progression free survival.
- Best overall response.
- Overall Response Rate Best overall response.
- Disease Control Rate All non-serious and serious adverse events (SAEs/AEs) and fatal outcomes.
- Impact of the activity level at baseline on the occurrence of adverse events.
- Proportion of subjects with termination due to SAEs/AEs.
- Proportion of subjects with dose reduction due to SAEs/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.

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