

# 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:** 05/01/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS108004

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### Study ID

199006


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### DARWIN EU® study

No

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### Study countries

 Austria

 Germany

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### 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.

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### 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 [Clinical.trials@ipsen.com](mailto:Clinical.trials@ipsen.com)

**Study contact**

[Clinical.trials@ipsen.com](mailto:Clinical.trials@ipsen.com)

### **Primary lead investigator**

Director Medical

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Actual: 26/07/2018

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### **Study start date**

Actual: 13/08/2018

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### **Data analysis start date**

Planned: 30/06/2027

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### **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

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

Not applicable

## Other study registration identification numbers and links

NCT03647878

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

Describe the use of Cabometyx™ (cabozantinib) tablets as monotherapy and the use of Cabometyx™ and Opdivo™ 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

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**Non-interventional study design, other**

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

## Study drug and medical condition

**Medicinal product name**

CABOMETYX

OPDIVO

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

CABOZANTINIB

NIVOLUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01EX07) cabozantinib

cabozantinib

(L01FF01) nivolumab

nivolumab

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**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)
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**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.
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## **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**

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

## Data sources

### Data sources (types)

Other

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

No