# 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

**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 clinical.trials@ipsen.com

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

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

Actual: 30/12/2020

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Primary data collection

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**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

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**Non-interventional study design, other**

Prospective, international, multicentre study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L01XE26) cabozantinib

cabozantinib

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**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)

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**Study report**

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

# 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

**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