CABOLIFE: A Prospective Non-Interventional Study on Effectiveness and Safety of Cabozantinib in Real-Life Setting for Previously Treated Patients with Neuroendocrine Tumours

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Study Planned

Administrative details

EU PAS number

EUPAS1000000752

Study ID

1000000752

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Germany

Study description

This study will assess how well cabozantinib works and how safe it is in adults with a type of cancer called neuroendocrine tumors (NETs).

These tumors can appear in all parts of the body. All participants in this study have already received at least one treatment that affects the whole body to help manage their cancer, but their disease has continued to grow.

The study will take place in regular hospitals and clinics in Germany and Austria.

It will follow about 150 participants who are taking cabozantinib as part of their usual care. Doctors will collect information from routine medical visits, tests, and scans to see how the cancer responds to treatment and how long participants stay on cabozantinib. They will also look at side effects and how the treatment affects participants' quality of life.

This is an observational study, which means that no extra tests or procedures will be done beyond what is normally used to care for participants with this condition.

Study status

Planned

Contact details

Study institution contact

Ipsen Clinical Study Enquiries clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Ipsen Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 13/08/2025

Actual: 13/08/2025

Study start date
Planned: 31/12/2025

Date of final study report
Planned: 31/12/2029

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

clin60000467 16.1.1 protocol V1.0 2025Jul30_Redacted.pdf (7.85 MB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Prospective, multicentre, non-interventional, single-arm study conducted in Germany and Austria with 150 adult participants with pNET or epNET. Observational period: up to 18 months wich includes 3-month follow-up if treatment discontinued.

Main study objective:

To describe the effectiveness of cabozantinib tablets in participantswith previously treated neuroendocrine tumours (NETs) in real-life in terms of disease control rate (DCR) at 6 months of cabozantinib treatment as assessed by the treating physician.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

CABOMETYX

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

CABOZANTINIB

Anatomical Therapeutic Chemical (ATC) code

(L01EX07) cabozantinib

cabozantinib

Medical condition to be studied

Pancreatic neuroendocrine tumour metastatic

Additional medical condition(s)

Unresectable or metastatic, well-differentiated pancreatic and extra-pancreatic neuroendocrine tumours (pNET/epNET) after prior systemic therapy

Population studied

Short description of the study population

150 adult participants in Austria and Germany who are prescribed cabozantinib tablets for unresectable or metastatic, well differentiated extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours who have progressed following at least one prior systemic therapy other than somatostatin analogues prior to entry into the study will be included.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)

        - Adults (18 to < 46 years)
        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

Study design details

Outcomes

Primary Outcome Measure:

- Disease Control Rate (DCR) at 6 Months

Secondary Outcome Measure:

- Objective Response Rate (ORR) up to 18 Months

- Change from baseline in global and subscale scores of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30 (EORTC QLQ-C30), at baseline and Every 3 Months up to 18 Months.

- Change from baseline in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Gastrointestinal Neuroendocrine Tumors Module (EORTC QLQ-GINET21), baseline and Every 3 Months up to 18 Months

- Percentage of participants experiencing Adverse Events (AEs), non-serious, drug-related, or serious Adverse Events (SAEs), up to 18 Months

- Frequency of Dose Modifications Due to Adverse Events, up to 18 months

- Duration of treatment (DoT), up to 18 Months

- Proportion of participants switching to a new line of therapy and type of therapy received, up to 18 Months

- Disease Control Rate After Switch to Next Line of Therapy, 3 Months After Therapy Switch
- Chromogranin A Levels, baseline and Every 3 Months up to 18 Months
- Neuron-Specific Enolase blood levels, baseline and Every 3 Months up to 18 Months
- Time to next treatment (TTNT), up to 18 Months
- Progression-Free Survival (PFS), up to 18 Months
- Progression-Free Survival Rate at 12 and 18 Months

Data analysis plan

In this non-interventional study, all the analyses will be primarily descriptive in nature.

The primary endpoint will be DCR of cabozantinib-treated NET participants; the rate of disease control will be presented with the 95% confidence interval (CI). Secondary endpoints, i.e. ORR, QoL, safety, DCR of subsequent treatment, DoT, as well as TTNT will be presented descriptively. The Kaplan-Meier method will be used to obtain the estimates of median PFS (time between the start of treatment with cabozantinib until progression assessed clinically or via imaging as observed by the treating physician or death from any cause) and their associated two-sided 95% CIs or landmark 12-month and 18-month PFS.

Subgroup analyses will be only performed if data permit and subgroups may be merged into larger subgroups if deemed necessary. The subgroups will be based of NET localization (Lung NET, Gastro-Intestinal NET, pNET and other NET).

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)

Non-interventional study

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