CASSIOPE

Non-interventional Study of Cabozantinib in Adults With Advanced Renal Cell Carcinoma

NCT-Nummer:
NCT03419572

Studienbeginn:
April 2018

Letztes Update:
24.02.2021

Wirkstoff:
-

Indikation (Clinical Trials):
Carcinoma, Carcinoma, Renal Cell

Geschlecht:
Alle

Altersgruppe:
Erwachsene (18+)

Phase:
-

Sponsor:
Ipsen

Collaborator:
-

Studien-Informationen

Detailed Description:

The study will follow the real-life management of patients in clinical practice. Visits will take place according to the study site's clinical practice. Cabozantinib is to be administered as directed by the investigator according to the study site's usual clinical

practice and the Cabometyx™ Summary of Product Characteristics (SmPC).

Ein-/Ausschlusskriterien

Inclusion Criteria:

- Age ≥18 years old

- Has a diagnosis of advanced RCC

- Has received at least one prior VEGF-targeted therapy

- For whom the treating physician has decided to start treatment with cabozantinib

tablets prior to inclusion

- No previous exposure to cabozantinib prior to inclusion

- Not concurrently involved in an interventional study

- Consents to participate in this noninterventional study

Exclusion Criteria:

- There are no exclusion criteria for this study.

Studien-Rationale

Primary outcome:

1. The proportion of subjects with dose modifications due to AEs (Time Frame - 12 months)

Secondary outcome:

1. Reason for cabozantinib dose modification (any modification, reduction, temporary interruption or discontinuation) (Time Frame - 12 months):
Percentage of subjects with the following reasons - Disease progression, Adverse event, Subject non-compliance, Treatment resumed or re escalated, Subject decision, Clinical / investigator decision, Other

2. Description of number of cabozantinib dose modifications (any modification, reduction, temporary interruption, increase or discontinuation) (Time Frame - 12 months)

3. Median time to first cabozantinib dose modification (any modification, reduction, temporary interruption, increase or discontinuation) due to AEs and for any reason (Time Frame - 12 months)

4. Description of cabozantinib starting dose (combination of dose per intake and frequency)

(Time Frame - 12 months)

5. Description of daily dose of cabozantinib received (Time Frame - 12 months)

6. Description of cabozantinib dose intensity (average daily dose compared to starting dose) (Time Frame - 12 months)

7. Duration of cabozantinib treatment (expressed as mean and median time to end of treatment) (Time Frame - 12 months)

8. Proportion of subjects with concomitant radiotherapies (Time Frame - 12 months)

9. Description of systemic therapy (drug name) planned following cabozantinib discontinuation (Time Frame - 12 months):
Percentage of subjects treated with the following drugs: Sunitinib, Pazopanib, Axitinib, Sorafenib, Bevacizumab, Cytokines, Everolimus, Lenvatinib, Nivolumab, Tivozanib, Experimental trial drug, Other, Unknown)

10. Overall best response (Time Frame - 12 months):
Per investigator assessment

11. Median Progression Free Survival (PFS) time (Time Frame - 12 months):
Defined as the time between the start date of cabozantinib and the date of progression or death. Clinical and radiographic (assessed by the investigator based on RECIST 1.1)

12. Overall Survival (OS) rate at the end of the study (Time Frame - 12 months)

13. Health care resource utilisation: number of visits to health care professionals (hospitalisation, surgical procedure, emergency room, physician, homecare by nurse) associated with the management of treatment-related AEs (Time Frame - 12 months)

14. Health care resource utilisation: Description of concomitant medications (by drug class and preferred name) associated with the management of treatment-related AEs (Time Frame - 12 months)

15. Health care resource utilisation: Description of number of unplanned laboratory tests associated with the management of treatment-related AEs (Time Frame - 12 months)

Studien-Arme

- Second line therapy
  Data collection
- Third and later line therapy
  Data collection

Geprüfte Regime

- Data collection:
  Only available evaluations as decided by the investigator based on local clinical practice

will be collected.

Studienleiter

Ipsen Medical Director
Study Director
Ipsen

Kontakt

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Quelle: ClinicalTrials.gov