CaboPoint: a Phase II study of cabozantinib as second-line treatment in patients with metastatic renal cell carcinoma

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Objective

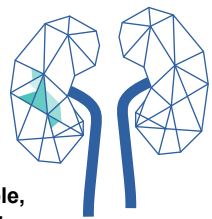
To investigate the

efficacy

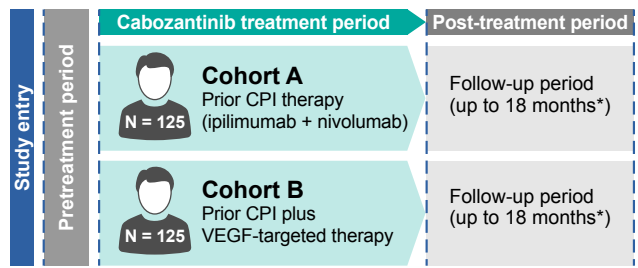
and

safety

of **2L cabozantinib** in **adults** with **unresectable, locally advanced RCC or metastatic RCC** with *a clear cell component*



Study periods



*After the date that the last patient recruited has received their first cabozantinib dose

End points

Primary end point

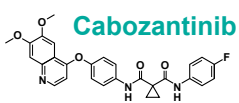
- ORR (*evaluated by independent central review*)*

Secondary end points

- DCR, DOR, PFS and TTR (*evaluated by independent central review*)*
- DCR, DOR, ORR, PFS and TTR (*evaluated by local investigator*)*
- OS
- FKSI-DRS†
- Safety and tolerability

*Based on RECIST version 1.1, and confirmed by a subsequent visit ≥28 days later. †Change in disease-related symptoms

Study treatment

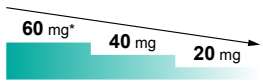


Cabozantinib

60 mg/day

Once daily

Dose reductions permitted



*Starting dose per protocol.

Eligibility criteria

Key inclusion criteria

- At least one target lesion*
- Disease progression†
- ECOG PS score of 0 or 1
- Adequate organ and marrow function

Key exclusion criteria

- Predominant non ccRCC
- Previous cabozantinib use
- Life expectancy <3 months
- Another active malignancy in the last 3 years

Other inclusion/exclusion criteria apply

*According to RECIST version 1.1. †Radiographic disease progression after treatment with CPI alone (cohort A) or CPI plus VEGF-targeted therapy other than cabozantinib (cohort B).

2L: Second-line; ccRCC: Clear cell RCC; CPI: Checkpoint inhibitor; DCR: Disease control rate; DOR: Duration of response; ECOG PS: Eastern Cooperative Oncology Group Performance Status; FKSI-DRS: Functional Assessment of Cancer Therapy–Kidney Symptom Index–Disease-Related Symptoms questionnaire; ORR: Objective response rate; OS: Overall survival; PFS: Progression-free survival; RCC: Renal cell carcinoma; RECIST: Response Evaluation Criteria in Solid Tumours; TTR: Time to response.