Protocol Title: CANTATA: A Randomized, Double-Blind, Placebo-Controlled Phase II Clinical Trial Comparing CB-839 in Combination with Cabozantinib (CB-Cabo) vs. Placebo with Cabozantinib (Pbo-Cabo) in Patients with Advanced or Metastatic Renal Cell Carcinoma (RCC)

Target Population: Advanced or Metastatic Renal Cell Carcinoma (RCC)

Summary: This clinical trial is a randomized Phase II evaluation of CB-839 (Telaglenastat) in combination with Cabozantinib versus placebo with Cabozantinib in Renal Cell Carcinoma patients with at least 1 and not more than 2 prior therapies in the advanced or metastatic setting.

Key Inclusion Criteria:
- Documented histological or cytological diagnosis of Renal Cell Carcinoma with a Clear-cell component
- Karnofsky Performance Score (KPS) ≥ 70%
- Measurable Disease per RECIST 1.1
- 1-2 lines of prior therapy for advanced or metastatic RCC including 1 anti-angiogenic therapy (any VEGF pathway-targeted agent used either as monotherapy or as a component of a combination regimen) OR the combination regimen of Nivolumab + Ipilimumab
- Adequate hepatic, renal, cardiac and hematologic function

Key Exclusion Criteria:
- Prior treatment with Cabozantinib (or other MET Inhibitor) or CB-839
- Receipt of other anticancer therapy within 2-6 Weeks, depending on the treatment
- Untreated or active brain metastases or CNS cancer
- Prior gastric surgery, small bowel resection, or other conditions that may impede adequate absorption of oral study drug
- Known active infection with HIV, Hepatitis B or C virus
- Inability to discontinue proton-pump-inhibitor use before randomization

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03428217