CANTATA: CB-839 With Cabozantinib vs. Cabozantinib With Placebo in Patients With Metastatic Renal Cell Carcinoma (CANTATA)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Sponsor:
Calithera Biosciences, Inc

Information provided by (Responsible Party):
Calithera Biosciences, Inc

ClinicalTrials.gov Identifier: NCT03428217

Recruitment Status: Active, not recruiting
First Posted: February 9, 2018
Last Update Posted: October 14, 2019

Study Description

Brief Summary:
This clinical trial is a randomized Phase 2 evaluation of CB-839 (telaglenastat) in combination with cabozantinib versus placebo with cabozantinib in patients with advanced or metastatic Renal Cell Carcinoma with a clear cell component.

Condition or disease
Intervention/treatment
Phase

Advanced Renal Cell Carcinoma
Drug: CB-839
Phase 2
Metastatic Renal Cell Carcinoma

Drug: Cabozantinib

Drug: Placebo

Detailed Description:
This clinical trial is a randomized Phase 2 evaluation of CB-839 (telaglenastat) in combination with cabozantinib versus placebo with cabozantinib in Renal Cell Carcinoma patients with at least one and not more than 2 prior therapies in the advanced or metastatic setting.

Study Design

Study Type: Interventional (Clinical Trial)

Actual Enrollment: 445 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Intervention Model Description: This is a double blinded placebo-controlled study where patients will be randomized 1:1 to either CB-839 (telaglenastat) plus cabozantinib or placebo plus cabozantinib

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Masking Description: Participants, care providers, investigators and outcomes assessors are blinded to treatment. Progression free survival (PFS) will be assessed by a blinded Independent Radiology Committee for the primary endpoint of the study.

Primary Purpose: Treatment

Official Title: A Randomized, Double-Blind, Placebo-Controlled Phase 2 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)

Actual Study Start Date: March 27, 2018

Estimated Primary Completion Date: September 30, 2020

Estimated Study Completion Date: September 30, 2022

Resource links provided by the National Library of Medicine

Drug Information available for: Cabozantinib

Genetic and Rare Diseases Information Center resources: Renal Cell Carcinoma

U.S. FDA Resources

Arms and Interventions
<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: CB-Cabo</td>
<td>CB-839 orally twice daily + cabozantinib orally once daily</td>
</tr>
<tr>
<td></td>
<td>Drug: CB-839</td>
</tr>
<tr>
<td></td>
<td>Oral glutaminase inhibitor</td>
</tr>
<tr>
<td></td>
<td>Other Name: Glutaminase inhibitor</td>
</tr>
<tr>
<td></td>
<td>Drug: Cabozantinib</td>
</tr>
<tr>
<td></td>
<td>Oral receptor tyrosine kinase inhibitor</td>
</tr>
<tr>
<td></td>
<td>Other Names:</td>
</tr>
<tr>
<td></td>
<td>• Cabometyx</td>
</tr>
<tr>
<td></td>
<td>• Cabometriq</td>
</tr>
<tr>
<td>Placebo Comparator: Pbo-Cabo</td>
<td>Placebo orally twice daily + cabozantinib orally once daily</td>
</tr>
<tr>
<td></td>
<td>Drug: Cabozantinib</td>
</tr>
<tr>
<td></td>
<td>Oral receptor tyrosine kinase inhibitor</td>
</tr>
<tr>
<td></td>
<td>Other Names:</td>
</tr>
<tr>
<td></td>
<td>• Cabometyx</td>
</tr>
<tr>
<td></td>
<td>• Cabometriq</td>
</tr>
<tr>
<td></td>
<td>Drug: Placebo</td>
</tr>
<tr>
<td></td>
<td>Placebo tablets</td>
</tr>
<tr>
<td></td>
<td>Other Name: Placebo Tablets</td>
</tr>
</tbody>
</table>

**Outcome Measures**

<table>
<thead>
<tr>
<th>Primary Outcome Measures</th>
<th>1. Progression Free Survival (PFS) [ Time Frame: 18 months ]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>An independent adjudication of radiological assessments will be conducted by Independent Radiology Committee (IRC) reviewing PFS per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1</td>
</tr>
</tbody>
</table>

**Secondary Outcome Measures**

<table>
<thead>
<tr>
<th>1. Overall Survival (OS) of study patients treated with CB-Cabo vs Pbo-Cabo [ Time Frame: 36 months ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessed by time from randomization to death by any cause</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. PFS of patients treated with CB-Cabo vs Pbo-Cabo [ Time Frame: 18 months ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessed by investigator per RECIST v1.1</td>
</tr>
</tbody>
</table>
Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Inclusion Criteria:

1. Documented histological or cytological diagnosis of renal cell carcinoma with a clear-cell component
2. Adult patients
3. Karnofsky Performance Score (KPS) \( \geq 70\% \)
4. Measurable Disease per RECIST 1.1
5. 1-2 lines of prior therapy for advanced or metastatic RCC including one 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
6. Adequate hepatic, renal, cardiac and hematologic function

Exclusion Criteria:

1. Prior treatment with cabozantinib (or other MET inhibitor) or CB-839
2. Receipt of other anticancer therapy within 2-6 weeks, depending on the treatment
3. Untreated or active brain metastases or central nervous system cancer, as defined per protocol
4. Prior gastric surgery, small bowel resection, or other conditions that may impede adequate absorption of oral study drug
5. Known active infection with HIV, Hepatitis B or C virus
6. Inability to discontinue proton-pump-inhibitor use before randomization
7. Patients who are pregnant or lactating

Contacts and Locations
Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):
NCT03428217

Show 133 Study Locations

Sponsors and Collaborators
Calithera Biosciences, Inc

Investigators
Study Director: Sam Whiting, M.D., Ph.D. Calithera Biosciences, Inc

More Information

Responsible Party: Calithera Biosciences, Inc
ClinicalTrials.gov Identifier: NCT03428217
Other Study ID Numbers: CX-839-008
First Posted: February 9, 2018
Last Update Posted: October 14, 2019
Last Verified: October 2019

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Calithera Biosciences, Inc:
Tumor Metabolism
RCC
Glutaminase Inhibitor
CB-839
CANTATA
TKI
Tyrosine Kinase Inhibitor
cabozantinib
Cabometyx

glutaminase
 glutamine
renal cell
clear cell
kidney cancer
cMET
MET
HGFR
telaglenastat
Additional relevant MeSH terms:

- Carcinoma
- Carcinoma, Renal Cell
- Neoplasms, Glandular and Epithelial
- Neoplasms by Histologic Type
- Neoplasms
- Adenocarcinoma

Kidney Neoplasms
Urologic Neoplasms
Urogenital Neoplasms
Neoplasms by Site
Kidney Diseases
Urologic Diseases