For Patients with Renal Cell Carcinoma

E2810 Available Through ECOG-ACRIN
Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy

Patient Population
See Section 3.0 for Complete Eligibility Details
- Must be at least 18 years of age with pathologically confirmed RCC with a clear cell component. Pure papillary and chromophobe histologies are excluded. There must be pathologic confirmation of metastatic disease in the resected metastatectomy specimen
- Must have undergone nephrectomy/partial nephrectomy to remove primary RCC (at any time in the past)
- Must have undergone surgical resection to remove 1(+) sites of metastatic disease, with successful removal of all known sites 2-12 weeks prior to randomization
- Patients with synchronous disease at initial diagnosis must have M1 disease (AJCC 7th ed. T1-4N0-1M1)
- Positive surgical margins are permitted if complete resection of gross metastatic disease is confirmed by the surgeon, and post-operative scans are negative
- Patients with metachronous disease with distant metastases, regional lymph node or renal bed recurrence are eligible (except recurrence at partial nephrectomy resection if it is the only site of disease)
- No kidney tumors without extrarenal sites of disease
- Must have no evidence of disease on post-op imaging
- No prior or concurrent systemic therapy for RCC
- No active peptic ulcer/inflammatory bowel disease
- No NYHA class II or greater congestive heart failure
- No prior history or current CNS metastases
- ECOG PS 0-1 and adequate lab values
- Must have no history of CVA, myocardial infarction, hospital stays for unstable angina, cardiac angioplasty, or stenting within 6 months of randomization
- Must not be taking strong CYP3A4 inhibitors, or drugs known to prolong the QTc interval

Treatment Plan
See Section 5.0 for Complete Treatment Details
Study arm assignment is double-blinded. Study treatment must begin between 4-14 weeks following metastatectomy

Arm A:
- Pazopanib 800 mg PO QD for 28 days
- Give drug continuously for 13 28-day cycles

Arm B:
- Placebo 800 mg PO QD for 28 days
- Give drug continuously for 13 28-day cycles

Notes:
- Pazopanib/Placebo should be taken without food (at least one hour before or two hours after a meal); it should be taken whole with water
- If a dose is missed, it should not be taken if it is less than 12 hours until the next dose
- No grapefruit products while taking study medication
- See protocol for HRQL assessment schedule

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

Please Enroll Your Eligible Patients!
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Schema

RCC M1 Resected to NED → Stratification: DFI ≤ or > 1 yr 1 or >1 site resected

Randomization

Arm A^1: Pazopanib PO Daily for 13 cycles

Arm B^1: Placebo PO Daily for 13 cycles

 Imaging every 3 months → Disease recurrence → Follow-up

Accrual Goal: 128 patients
Cycle: 28 days
NOTE: QOL will be assessed at several timepoints during this study. See Section 5.3.1 for details of the assessment schedule.

1. Blinded treatment:
   Arm A= Pazopanib 4 tablets PO daily
   Arm B= Placebo 4 tablets PO daily