KCRC Kidney Cancer RESEARCH CONSORTIUM

Phase 1b/2 trial of Ipilimumab, Nivolumab, and Ciforadenant (adenosine A2a receptor antagonist) in first-line advanced renal cell carcinoma

WILL ENROLL
50 patients

at

4 KCRC SITES:
Vanderbilt University
University of Pennsylvania
MD Anderson Cancer Center
Duke University

Initiating Site:
Dr. Katy Beckerman, Vanderbilt University

Summary: Study goal is to learn if the combination of ciforadenant, ipilumumab, and nivolumab can help control advanced renal cell carcinoma.

Treatment with ipilimumab and nivolumab as a combination is FDA-approved. Ciforadenant is not FDA-approved or commercially available. The combination of ciforadenant, ipilimumab, and nivolumab is investigational. Receiving treatment on the study drugs may help control the patient's disease. The patient may also receive no benefit from treatment. Future patients may benefit from the information learned in this study.

Trial Schema

LEAD-IN SAFETY PHASE 1B

N = 8

Ipilimumab 1 mg/kg IV q3w
+
Nivolumab 3 mg/kg IV q3w
+
Ciforadenant 100 mg PO BID

DOSE-EXPANSION PHASE 2

N = 42

Ipilimumab 1 mg/kg IV q3w
+
Nivolumab 3 mg/kg IV q3w
+
Ciforadenant 100 mg PO BID

Key Criteria

- Clear Cell Renal Cell Carcinoma
- Stage IV Metastatic Disease
- No Prior Systemic Therapy
- ECOG 0, 1
- Tumor Sample for Histologic Confirmation & Biomarker Assessment
- Adequate Organ Function

WOCBP: Women Of Child-Bearing Potential must not be pregnant and must utilize two forms of contraception while on treatment and for 23 weeks after treatment.

Men who are sexually active with WOCBP must agree to utilize acceptable contraception while on treatment and for 31 weeks after.

Costs: Ciforadenant is provided by the study at no cost to the patient. The patient's insurance will be billed for nivolumab and ipilimumab.

Drug Frequency: Ipilimumab is given 4 times (every 3 weeks). Nivolumab is given 4 times (every 3 weeks), then every 4 weeks, as long as recommended by the study doctor. Ciforadenant is taken daily as long as recommended by the study doctor.

Clinic Visit Frequency: Every 3 weeks for 4 visits, then every 4 weeks until study treatment is completed. Two additional visits at 30 days and 100 days post-study treatment.