KCRC Kidney Cancer RESEARCH CONSORTIUM

Phase 2 Study of Combination Tivozanib and Nivolumab in Advanced Non-Clear Cell Renal Cell Carcinoma (FORTUNE)

WILL ENROLL
50 patients

at

3 KCRC SITES:
MD Anderson Cancer Center
University of Michigam
University of Pennsylvania

Initiating Site:
University of Michigan
Dr. Ajjai Alva & Dr. Charles Nguyen

Summary: Study goal is to determine if the combination of tivozanib and nivolumab can help control advanced non-clear cell renal cell carcinoma.

Treatment with nivolumab is FDA approved. Treatment with tivozanib is FDA approved for other types of renal cell carcinoma but not non-clear cell renal cell carcinoma. The combination of nivolumab and tivozanib 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

Advanced Non-Clear RCC
(treatment-naive & previously treated)

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PO Tivozanib
0.89 mg daily D1-21 in 28-day cycles
+ IV nivolumab 480 mg q4 weeks

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Stage One:
n = 23 *

** A maximum of 5 patients with chromophobe histology will be allowed to enroll in first stage*

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If 3 or fewer patients respond, study will be terminated.

If 4 or more patients respond, 25 additional patients will be enrolled.

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Imaging every 2 cycles (8 weeks) x 3, followed by imaging every 3 cycles (12 weeks) thereafter

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Continue until progression, death, consent withdrawal, or intolerable toxicity

Key Criteria

- Non-Clear Cell Renal Cell Carcinoma
- Stage IV Metastatic Disease
- Up to One Line of 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.

Drug Frequency: Nivolumab is given every 4 weeks as long as the study doctor thinks it is in the patient's best interest. Tivozanib is taken daily for 21 days then a break of 7 days is given as long as the study doctor thinks it is in the patient's best interest.

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

Clinic Visit Frequency: Every 4 weeks until study treatment is completed. One additional visit at 30 days post-study treatment.