KCRC Kidney Cancer RESEARCH CONSORTIUM

# A phase II study bolstering outcomes by optimizing immunotherapy strategies with evolocumab and nivolumab in patients with metastatic renal cell carcinoma (BOOST-RCC)

WILL INITIALLY ENROLL
**10 patients** *at*

TWO KCRC SITES:
MD ANDERSON
UT SOUTHWESTERN

**Initiating Site:**
**Dr. Tian Zhang, UT Southwestern**

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

The combination of evolocumab and nivolumab is investigational. Receiving treatment on the study drugs may help control the patient's disease but the patient may also receive no benefit from treatment. There is potential for future patients to benefit from the information learned in this study.

## Trial Schema

### Metastatic Renal Cell Carcinoma

- Progression on or after prior PD-1 inhibitor ( greater than 6 months)
- Progression on prior VEGF inhibitor (could be in combination with PD-1 inhibitor)
- Radiographically evident disease

PCSK9 Inhibitor Evolocumab
Q4 Weeks
+
Nivolumab 480 mg IV
Q4 Weeks

**Stage One:**
n = 10

** Also safety lead-in for combination treatment in first five patients.*
** Paired biopsies for up to ten patients.*

If zero patients respond, study will be terminated.

Treatment discontinued if disease progresses or patient experiences intolerable adverse event.

**Stage Two:**
n = 19
If one or more patients respond, study expanded.

**Primary Objective:**
Objective Response Rate

## Key Criteria

- Clear Cell Renal Cell Carcinoma
- Stage IV Metastatic Disease
- Prior Treatment with VEGF and/or Immune Therapy Agents
- ECOG 0, 1
- 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. Cannot breastfeed while receiving treatment.*

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

**Costs:** Evolocumab and nivolumab is provided by the study at no cost to the patient.

**Drug Frequency:** Evolocumab is given every 4 weeks. Nivolumab is given every 4 weeks, as long as the study doctor thinks it is in the patient's best interest.

**Clinic Visit Frequency:** Every 4 weeks until study treatment is completed. Then at 30 days and 100 days after study treatment is completed.