KCRC Kidney Cancer RESEARCH CONSORTIUM

Belzutifan's Role in Active surveillance Versus treatment for indolent metastatic clear cell Renal Cell Carcinoma (BRAVE-RCC)

ENROLLMENT:
78 patients

at

KCRC SITES:
Duke University
MD Anderson Cancer Center
UT Southwestern
Vanderbilt University

Initiating Site:
UT Southwestern
Dr. Tian Zhang and Dr. Janie Qin

Summary: The goal of this clinical research study is to learn if belzutifan can help to control the disease in patients with metastatic RCC who are considered candidates for active surveillance and have not undergone previous systemic treatment.

Belzutifan is FDA approved and commercially available for patients with advanced RCC who have undergone previous PD-1, PD-L1, or VEGF-TKI therapy. In this study, it is being used for research purposes only.

Trial Schema

78 eligible patients,
randomized 2:1 into two arms:

N = 52	N = 26
Belzutifan, 120 mg PO daily	Active Surveillance
Standard of care, physician's choice next line therapy	

Primary Endpoints:
- Progression-free survival

Secondary Endpoints:
- Objective response rates
- Time to start of new systemic treatment
- PFS2
- Safety profile
- Quality of life measures
- Overall survival

Key Criteria

- Clear Cell Renal Cell Carcinoma
- Stage IV Metastatic Disease
- ECOG 0, 1
- Radiologically evident disease (measurable by RECIST 1.1)
- Adequate Organ Function
- No prior treatment for RCC; clinically appropriate for active surveillance

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: If in treatment group, you will take 120 mg of Belzutifan daily.

Costs: If in treatment group, the study drug belzutifan will be provided at no cost to you while on the study. If in the observation group, you and/or your insurance provider will be responsible for any costs related to active surveillance.

Clinic Visit Frequency: Patients will visit clinic every 4 weeks (four times), then every 6 weeks until end of treatment. Then one more visit at 30 days after study treatment is completed.