KCRC Kidney Cancer RESEARCH CONSORTIUM

A multi-center, open-label phase II study of lenvatinib plus pembrolizumab (LEAP) in renal cell carcinoma patients with brain metastasis previously treated with immune checkpoint blockade

WILL ENROLL
40 patients

at

Initiating Site:
MD Anderson Cancer Center
Dr. Eric Jonasch

Summary: The study's goal is to determine if the combination of lenvatinib and pembrolizumab can help control renal cell carcinoma in patients with brain metastases.

The combination of lenvatinib and pembrolizumab in this setting 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

Renal Cell Carcinoma
with brain metastases, extracranial disease not required

Enrollment
Screening/Eligibility
N = 40

Run-In Safety Assessment
(first 5 patients)

Pembrolizumab
200 mg IV D1 Q3W
+
Lenvatinib
20 mg PO QD

Treatment for a maximum of 24 months (35 cycles) in the absence of disease progression or toxicity.

Key Criteria

- Renal Cell Carcinoma
- Brain Metastases, Extracranial Disease Not Required
- Prior treatment with Anti-PD-1/L1
- 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: Lenvatinib is taken daily. Pembrolizumab is given every 3 weeks. Treatment is for a maximum of 24 months as recommended by the study doctor.

Costs: Lenvatinib and pembrolizumab are provided by the study at no cost to the patient.

Clinic Visit Frequency: Every 3 weeks until study treatment is completed; then, at 28 days and 84 days after study treatment is completed.

For more information: info@kidneycancerconsortium.org