GENITOURINARY ONCOLOGY

CLINICAL TRIALS

KIDNEY CANCER & NEUROENDOCRINE TUMORS

Phase II Trial of an Alternative Cabozantinib Dosing Schedule in Metastatic Renal Cell Carcinoma & Neuroendocrine Tumors

Goal: To assess alternative dose regimens of cabozantinib to optimize efficacy and toxicity

Setting: Treatment-Naïve and Treatment-Refractory Metastatic Disease

Drugs: Cabozantinib +/- Nivolumab

Cohorts:

COHORT A: Cabozantinib alone for patients who have had any number of prior therapies or are not eligible for immunotherapy

COHORT B: Cabozantinib + Nivolumab for treatment-naïve patients

COHORT C: Neuroendocrine tumors

Key Eligibility Criteria:

1. Clear cell OR non-clear cell disease
2. Measurable disease
3. No uncontrolled HTN
4. No disease invading or encasing major blood vessels
5. No cavitating lung lesions
6. No cardiac interventions within 6 months

BLADDER CANCER

Increasing Pre-Surgical Identification of Muscle Invasive Tumor Evaluations Prior to Planned Cystectomy (INSITE Trial)

Goal: The primary goal of this study is to evaluate the utility of seeT0 endoscopic assessment paired with a blood-based ctDNA assay collected prior to cystectomy in predicting patients with no muscle invasive (pT<2) tumor in final pathologic bladder specimen.

Setting: Neoadjuvant for MIBC and Treatment-Refractory NMIBC

Key Eligibility Criteria:

All patients opting to get a cystectomy (bladder removal) for bladder cancer, including both muscle-invasive (MIBC) and non-muscle-invasive (NMIBC)

Contact Us

For more information about these clinical trials or to refer a patient, call Alexa Gerchman **215-728-3568**. As new trials are regularly introduced, visit **FoxChase.org/ClinicalTrials** for the latest updates.

Key Account Management Team

If you have any questions, our Key Account Management team is here to help you. Our Key Account Managers can offer a seamless introduction to our specialists, obtain a patient appointment, and answer any questions or concerns you have. Contact our team at **KeyAccountManager@fccc.edu**.

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UROTHELIAL CANCER

A Phase II Pilot Trial of Enfortumab Vedotin Schedule De-escalation in Metastatic Urothelial Carcinoma

Goal: To assess alternative dose regimens of Enfortumab Vedotin to optimize efficacy and toxicity

Setting: Treatment-Naïve and Treatment-Refractory Metastatic Disease

Cohorts:

COHORT A: Enfortumab Vedotin alone for patients who have had or are not eligible for immunotherapy

COHORT B: Enfortumab Vedotin + Pembrolizumab for treatment-naïve patients

Key Eligibility Criteria:

1. Measurable Disease
2. ECOG 0-2
3. 2-wk washout prior Tx if relevant
4. No uncontrolled diabetes
5. No current Abx for an infection
6. No grade 2 baseline sensory or motor neuropathy
7. No Uncontrolled/untreated CNS Mets

Phase II, Double-Blind Study of Pembrolizumab +/- V940 (mRNA-Based Bespoke Vaccine) in Urothelial Carcinoma Post-Radical Resection

Goal: Addition of vaccine or placebo to adjuvant pembrolizumab to improve recurrence-free survival

Setting: Adjuvant Urothelial Carcinoma

Drugs: Pembrolizumab + V940 Vaccine/Placebo

Key Eligibility Criteria:

1. Muscle invasive urothelial carcinoma from any primary tract site (urothelial > 50% histology)
2. Upper tract capped at 20% and cysto required in screening
3. Stages:
   a. Prior cisplatin-based neoadjuvant chemo: ypT2-4a and/or ypN+
   b. No prior chemotherapy: pT3-4a and/or pN+
4. Must sign consent within 8 wks of surgery and be randomized within 16 weeks
5. No active autoimmune disease
6. CrCl must be ≥ 30 mL/min

PROSTATE CANCER

Phase 3 Study of Xaluritamig vs Cabazitaxel or Second Androgen Receptor-Directed Therapy in Subjects With Progressive Metastatic Castration-Resistant Prostate Cancer

Goal: To compare overall survival (OS) in subjects receiving xaluritamig vs investigator's choice (cabazitaxel or second androgen receptor-directed therapy [ARDT]

Setting: Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Drug: Randomized to Xaluritamig or Investigators Choice (Abiraterone/Enzalutamide/Cabazitaxel)

Key Eligibility Criteria:

1. Adenocarcinoma of the Prostate
2. mCRPC with ≥ 1 Metastatic Lesion on Baseline CT, MRI, or Bone Scan
3. Evidence of Progression
4. PSA progression defined as 2 consecutive increases minimum 1 week apart (Minimum PA start 2.0 ng/mL)
5. Increase of >/= 20% in sum of all soft tissue target lesions
6. Bone Disease evaluable disease or new bone lesion by bone scan
7. Prior treatment with at least one ARDT/One Taxane Therapy
8. No Active Autoimmune Disease that requires systemic therapy
9. Recent MI within 12 months

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