

MD Anderson Cancer Center Clinical Trials for Urologic/ Genitourinary Cancers

To refer online: <https://my.mdanderson.org>

To refer a patient, call the Genitourinary Cancer Center: 866-363-1332

To discuss genitourinary clinical trials, call Cherie Perez, research nurse: 713-563-1602

10/2014

PROSTATE CANCER

Prostate Intact (No Prior Hormones)

2005- 0619 (P.I. Jeri Kim, M.D.) Active Surveillance in Prostate Cancer: a Prospective Cohort Study

2012-0104 (P.I. Steven Frank, M.D.) Phase II Study Assessing the Potential for Reduced Toxicity Using Focal Brachytherapy in Low-Risk Prostate Cancer

2012-1003 (P.I. Thomas Pugh, M.D.) Phase II Trial of Hypofractionated Proton Beam Therapy in Men with Localized Prostate Adenocarcinoma

2012-1013 (P.I. Thomas Pugh, M.D.) Pilot Study for the Identification of MRI Markers in Prostate Brachytherapy

Prostate Intact (Limited or No Prior Hormones)

RTOG1115 (P.I. Thomas Pugh, M.D.) Phase III Trial of Dose-Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist Versus Dose-Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High-Risk Prostate Cancer

2013-0982 (P.I. Karen Hoffman, M.D.) A Phase II Trial of Abiraterone acetate, Radiotherapy and Short-Term Androgen Deprivation in Men with Unfavorable Risk Localized Prostate Cancer

Neoadjuvant

2013-0332 (P.I. Christopher Logothetis, M.D.) A Pre-Operative Study to Assess the Effects of Abiraterone Acetate Plus LHRH Agonist and Abiraterone Acetate Plus LHRH Agonist and Enzalutamide for Six Months for Prostate Cancer Patients at High Risk for Recurrence Pathology

Suspect Lymph Nodes

2011-0231 (P.I. Amado Zurita, M.D.) Presurgical Androgen Deprivation Therapy with or without

Axitinib in Previously Untreated Prostate Cancer Patients with Known or Suspected Lymph Node Metastasis

Prostate Intact Metastatic

2012-0705 (P.I. Brian F. Chapin, M.D.) Phase II Randomized Trial of Best Systemic Therapy or Best Systemic Therapy plus Definitive Treatment (Radiation or Surgery) of the Primary Tumor in Metastatic Prostate Cancer

Castrate Sensitive Prostate Cancer with Biochemical Failure Only

2012-0993 (P.I. Christopher Logothetis, M.D.) Randomized Study of Finite Androgen Ablation Versus Finite Androgen Ablation in Combination with Abiraterone Acetate and Prednisone in Patients with Prostate Cancer Who Have PSA Progression After Prostatectomy and/or Radiotherapy

Castrate Sensitive Prostate Cancer with Metastatic Disease

2012-0252 (P.I. Paul Corn, M.D., Ph.D.) An Observational Study of XL-184 (Cabozantinib) and Androgen Ablation in Patients with Androgen Dependent Metastatic Prostate Cancer

Castrate Resistance

2011-0381 (P.I. John Araujo, M.D., Ph.D.) A Phase I/II Open-Label, Multiple-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of VT-464 in Chemotherapy-Naive Patients with Castration-Refractory Prostate Cancer

Metastatic Disease with Evidence of Progression (adenocarcinoma or small cell or anaplastic)

2011-0727 (P.I. Paul Corn, M.D., Ph.D.) Phase I/II Open-Label Study of Cabazitaxel with or without

Carboplatin in Patients with Metastatic Castration-Resistant Prostate Cancer

Metastatic Disease with Evidence of Progression

2013-0086 (P.I. Paul Corn, M.D., Ph.D.) A Phase I/II Study of Dovitinib (TKI258) Combined with Abiraterone Acetate in patients with Metastatic Castrate Resistant Prostate Cancer Evaluating Markers of FGF and AR Signaling in Bone Marrow and Plasma

Metastatic Disease with Biopsy Accessible Site

2012-1038 (P.I. Paul Corn, M.D., Ph.D.) A Randomized Gene Fusion Stratified Phase II Trial of Abiraterone with or Without ABT-888 for Patients with Metastatic Castration-Resistant Prostate Cancer

Metastatic Disease with Documented Bone Mets

2014-0026 (P.I. John Araujo, M.D. Ph.D.) A Phase 2 Study of Oral Selinexor (KPT-330) in Metastatic Castrate Resistant Prostate Adenocarcinoma

2013-0933 (P.I. John Araujo MD, Ph.D.) An Observation, Open Label Study of Alpharadin (Radium 223) in Patients with Castrate Resistant Prostate Cancer Bone Metastases

Metastatic Disease with BMI defined as obese

2010-0369 (P.I. Lance Pagliaro, M.D.) First-in-Man, Phase I Evaluation of a Single Cycle of Prohibitin Targeting Peptide 1 in Patients with Castration-Resistant Prostate Cancer and No Standard Treatment Options

IMMUNOTHERAPY

2013-0444 *NCT02113657* (P.I. Pam Sharma & Sumit Subudhi M.D. Ph.D.) An observational study to determine T-cell responses to neoantigens following treatment with ipilimumab in men with metastatic castration resistant prostate carcinoma

RENAL CELL CARCINOMA

Predominant Clear Cell Not Metastatic

2013-0600 (P.I. Christopher Wood, M.D.) Neoadjuvant Pazopanib: a Phase II Study to Evaluate the Effect on Disease Response and Recurrence and to Report on Possible Predictive Biomarkers of Drug Activity in Renal Cell Carcinoma

Metastatic Presurgical

2012-0885 (P.I. Christopher Wood, M.D.) International Phase III Randomized Trial of Autologous Dendritic Cell Immunotherapy Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)

Metastasectomy

2009-0038 (P.I. Eric Jonasch, M.D.) Phase II Metastasectomy Study for Patients with Renal Cell Carcinoma

Untreated Predominant Clear Cell

2010-0085 (P.I. Nizar M. Tannir, M.D.) Sequential Two-Agent Assessment in Renal Cell Carcinoma Therapy: the START Trial

2011-0358 (P.I. Nizar M. Tannir, M.D.) Phase II Randomized Trial of Pazopanib Versus Temsirolimus in Poor-Risk Clear Cell Renal Cell Carcinoma

2013-0944 *NCT02060370* (P.I. Eric Jonasch M.D.) A Phase II Study of Alternative Sunitinib Scheduling in Patients with Metastatic Renal Cell Carcinoma (mRCC)

**Previously Treated with Immunotherapy
Predominant Clear Cell**

2010-0085 (P.I. Nizar M. Tannir, M.D.) Sequential Two-Agent Assessment in Renal Cell Carcinoma Therapy: the START Trial

Previously Treated Predominant Clear Cell

2013-0580 (P.I. Nizar Tannir, M.D.) A Phase 3 Randomized Controlled Study of Cabozantinib (XL184) vs Everolimus in Patients with Metastatic Renal Cell Carcinoma That Is Refractory to or has Progressed After Prior VEGFR Tyrosine Kinase Inhibitor Therapy

Von Hippel-Lindau Syndrome

2011-0465 (P.I. Eric Jonasch, M.D.) Phase II Trial of Pazopanib in Von Hippel-Lindau Syndrome

UROTHELIAL CANCERS

Locally Advanced

SWOGS1011 (P.I. Jay B. Shah, M.D.) Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle-Invasive Urothelial Cancer

Phase I Strategies

2009-0825 (P.I. Arlene Siefker-Radtke, M.D.) Phase I Study of Systemic Gene Therapy with SGT-94 in Patients with Solid Tumors.

Urothelial Rare Tumor Types

2007-0933 (P.I. Seungtaek Choi, M.D.) Prophylactic Cranial Irradiation (PCI) for Patients with Small Cell Carcinoma of the Urothelium