GU Cancer Clinical Trials

**Non-Metastatic**

UCI 16-19 ATLAS: A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy (Uchio)

UCI 16-90 A Phase III, Multicenter, Randomized Study Of Atezolizumab (Anti-PD-L1 Antibody) In Combination With Enzalutamide Versus Enzalutamide Alone In Patients With Metastatic Castration-Resistant Prostate Cancer After Failure Of An Androgen Synthesis Inhibitor And Failure Of, Ineligibility For, Or Refusal Of A Taxane Regimen (Mar)

UCI 17-10 A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial Testing Ipatasertib plus Abiraterone plus Prednisone/ Prednisolone, Relative to Placebo plus Abiraterone plus Prednisone/ Prednisolone in Adult Male Patients with Asymptomatic or Mildly Symptomatic, Previously Untreated, Metastatic Castrate-Resistant Prostate Cancer (Mar)

UCI 17-25** A Phase 2, Open-Label, 2-Arm, Response Rate Study of Talazoparib in Men With DNA Repair Defects and Metastatic Castration-Resistant Prostate Cancer Who Previously Received Taxane-Based Chemotherapy and Progressed on at Least 1 Novel Hormonal Agent (Enzalutamide and/or Abiraterone Acetate/ Prednisone) (Uchio)

UCI 17-41** A Multi-Center, Randomized, Assessor-Blind, Controlled Trial Comparing the Occurrence of Major Adverse Cardiovascular Events (MACEs) in Patients with Prostate Cancer and Cardiovascular Disease Receiving Degarelix (GnRH Receptor Antagonist) or Leuprolide (GnRH Receptor Agonist) (Uchio)

UCI 17-86** Phase 1 Trial of Efficacy and Feasibility of Robot Assisted Salvage Pelvic Lymph Node Dissection (RS-PLND) or Robot Assisted Salvage Pelvic Mass Resection (RS-PMR) Post-Robot Assisted Radical Prostatectomy (Ahlering)

**Metastatic**

UCI 16-76 Phase Ib/II Trial of Pembrolizumab (MK-3475) Combination Therapies in Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-365) (Mar)

UCI 17-48 HERO: A Multinational Phase 3 Randomized, Open-label, Parallel Group Study to Evaluate the Safety and Efficacy of Relugolix in Men with Advanced Prostate Cancer (Uchio)

**Both**

UCI 17-42 A Phase III, Randomized, Multicenter Trial of Durvalumab (Anti-PD-L1 Antibody) In Combination With Carboplatin and Paclitaxel Versus Carboplatin plus Paclitaxel in Subjects With Locally Advanced or Non-Metastatic, Platinum-Containing Resistant Bladder Cancer (Mar)

**Opening soon**

For more details contact 1-877-UC-STUDY or ucstudy@uci.edu

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**UCI 16-17** A Phase I/II, Open Label, Safety and Efficacy Trial of Intravesical CG0070 and CTLA 4 Blockade as a Neo-Adjuvant Regimen for Muscle Invasive Bladder Cancer (*MIBC*) Patients Selected for Radical Cystectomy (Uchio)

**UCI 16-68** A Phase III Randomized, Controlled Clinical Trial of Pembrolizumab with or without Platinum-Based Combination Chemotherapy versus Chemotherapy in Subjects with Advanced or Metastatic Urothelial Carcinoma (Uchio)

**UCI 15-77** A Phase II Clinical Trial to study the efficacy and safety of Pembrolizumab (MK-3475) in subjects with high risk non-muscle invasive bladder cancer (NMIBC) unresponsive to Bacillus Calmette-Guerin (BCG) therapy (Uchio)

**UCI 17-18** A Single-Arm, Open-Label, Multicenter Study of Enfortumab Vedotin (ASG-22CE) for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer who Previously Received Immune Checkpoint Inhibitor (CPI) Therapy (Mar)

**UCI 17-42** A Randomized, Multicenter, Two-Arm, Single-Dose, Double-Blind, Placebo-COrntrolled Phase 3 Study of Intravesical Qapzola™ (Apaziquone) as a Chemotherapy Adjuvant to TransUrEthr Resection of Bladder Tumors in Patients with Low- to Intermediate-Risk Non-Muscle Invasive Bladder Cancer (CONQUER) (Uchio)

**UCI 17-74** A Phase 3 randomized, Double-Blind Clinical Study of Pembrolizumab + Epacadostat vs Pembrolizumab + Placebo as a Treatment for Recurrent or Progressive Metastatic Urothelial Carcinoma in Patients who have Failed a First-Line Platinum-containing Chemotherapy Regimen for Advanced/Metastatic Disease (Uchio)

**UCI 17-75** A Phase 3 Randomized, Double-Blind Trial of Pembrolizumab (MK-3475) in Combination with Epacadostat (INCB024360) or Placebo in Participants with Cisplatin-ineligible Urothelial Carcinoma (KEYNOTE-672/ECHO-307) (Uchio)

**SUSPENDED** UCI 15-22 Electro-Phage and Colorimetric Aplamer Sensors for Clinical Staging and Monitoring of Bladder Cancer (Landman)

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**Prostate/Renal**

* SUSPENDED* UCI 16-01 Pathway Analyses for Individualized Network Therapeutics for Cancer (PAINT Cancer) (Nelson)

**Prostate/Bladder**

UCI 17-90 A Two-Part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients with HER2-Positive Solid Tumors Whose Disease Progressed on Prior HER2 Targeted Therapy (Ou)

**Renal**

UCI 07-40 Phase 1 Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, a C-MET/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer (Ou)

**BASKET TRIALS**

ECOG EAY131 Molecular Analysis for Therapy Choice (MATCH) (Bota)

SWOG S1609 DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Bota)
- 17: Epithelial tumors of penis - squamous adenocarcinoma cell carcinoma with variants of penis
- 18: Squamous cell carcinoma variants of the GU system
- 19: Spindle cell carcinoma of kidney, pelvis, ureter
- 20: Adenocarcinoma with variants of GU system (excluding prostate cancer)
- 33: NOC Rare Tumors, after discussion with Study Chairs

UCI 16-96 A Phase 1 Study of the Highly-selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors (Ou)

UCI 17-50 A Multicenter, Phase 1/1b, Open-Label, Dose-Escalation Study of ABBV-399, an Antibody Drug Conjugate, in Subjects with Advanced Solid Tumors (Ou)

**Opening soon**

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