

## Prioritization List

Department: Genitourinary Center

**GU CENTER Protocol Priority List** edited by Cherie Perez 5/11/2011 Red = pre-active trial

### **PHASE I TRIALS FOR GU CANCERS see disease site for specifics**

solid tumor	2009-0825 SGT94 activation pending
solid tumor	2010-0030 Avicin D phase I activation pending
Urothelial	2006-0014 bortezomib gem adria
Prostate	2008-0395 BMTP-11 must have + bone marrow
Prostate	2008-0606 lenalidomide paclitaxel LN preferred but not required
Prostate	2010-0369 Prohibitin Targeting Peptide 1 for CRPC activation pending
Renal	2009-0037 sunitinib temsirolimus
Renal	200-0907 SGN-75 for CD70 + patients

### **TRIALS FOR GU CENTER PATIENTS**

**2009-0825 NCT pnd** Randall Millikan MD PhD/TBN RN 0/24 **IRB 6/2/2010 NOT Activated** A Phase I Study of Systemic Gene Therapy **SGT94-01** in patients with **Solid Tumors** [Pts with solid tumors with no standard therapy; preference to those with absent expression of RB protein by IHC in blocks; spirometry 70%; LVEF >=45%; recovery of 4-8 wks depending on last tx] **SGT-94 requires negative pressure room approved for gene therapy**

**2010-0030 NCT pnd** John Araujo MD PhD/TBN RN 0/0 multicenter 30-35 **NOT Activated IRB 2/25/10** A Multicenter **Phase 1** Study of **Avicin D** Delivered by **Subcutaneous** Injection in Patients with Advanced Solid Tumors [histologically confirmed, advanced solid tumor refractory to or intolerant of established therapy known to provide clinical benefit for their condition] pt must have investigational agent injection given at MDACC may not be self taught

### **GERM CELL TUMORS**

#### **UNTREATED**

**DM02-056 NCT00104676** Lance Pagliaro MD/Donnah Jones RN 26/76 **RE Activation PENDING contract (CNPE 4/7/09)** A risk adapted strategy of the use of **dose dense chemotherapy** in patients with poor prognosis disseminated non seminomatous germ cell tumors a phase III trial [16 yrs+; NSGCT by histologic exam or clinical evidence and elevated serum HCG or AFP levels (in case of clinical emergency, therapy can be started before pathologic sample is obtained if tumor markers are elevated); Testicular, retroperitoneal, or mediastinal primary site; Evidence of disseminated disease (clinical stages II or III); classified as poor prognosis according to IGCCCG criteria: a) Primary mediastinal NSGCT (any stage) or b) Non-pulmonary visceral metastases or c) HCG > 50,000 UI/l, or AFP > 10,000 ng/ml, or LDH > 10 times the upper normal value; No prior chemotherapy.] oxiliplatin only provided; course 1 = BEP course 2 is randomized to BEP vs Dose-Dense Sequential T-BEP-Oxali/Cisplat-Ifo-Bleo

### **PENILE**

**2009-0505 Surena Matin MD/RN TBN 5/10 activated 3/17/2010** Feasibility and outcomes of video endoscopic inguinal lymph node dissection (**VEIL**) in patients with Penile Squamous Cell Carcinoma [high risk features as determined by urologic evaluation; agree to follow-up assessments by telephone; cannot have co-morbidities that prevent surgical treatment of regional disease]

### **PROSTATE**

[See the attachment for a quick view below](#)

\*\*\*\*\* PROSTATE QUICK LOOK v14 cap.\*\*\*\*\*

### **A. NEWLY DIAGNOSED primary ADENOCARCINOMA histology SURVEILLANCE**

**2005-0619 NCT00490763** Jeri Kim MD/Victoria Brown RN 477/750 Activated 2/13/2006 Active **Surveillance** in Prostate Cancer: A Prospective Cohort Study [clinically localized defined by path & PSA to be **very low-risk/low-risk**, clinically localized cancer [**not low-risk**] who refuse early intervention or chose active surveillance, clinically localized cancer precluded from local therapy because of comorbidities; Histologic proof within 6 mos of entry; agree to repeat extended

11-core multisite bx (midline, & 2 cores left/right anterior horn) of the prostate at study entry]

## NEW TECHNOLOGY

**2008-0244** John **Ward** MD/Virginia **Sarmiento-Marin** 39/100 activated 4/6/09 **Conformal Cryotherapy** for Localized Adenocarcinoma of the Prostate [confirmed, organ confined adenoca by 10 core biopsy, **NO PRIOR hormones**, PSA </= 10ng/mL before prostate biopsy]

## PROSTATECTOMY

**2006-0614 DCP 03-1-03** *NCT00438464* Jeri **Kim** MD/Deborah **Harris** RN 181/200 multi 200 Activated 2/15/07 (held 12/12/2008 to 5/13/2009) A Randomized, Placebo Controlled Study of the Tissue Effects of **Finasteride** in Presurgical Patients with clinically Organ Confined Prostate Cancer [Scheduled for prostatectomy 4-6 weeks from study entry, cT1c or T2, Gleason <= 7, PSA < 10 ng/mL within 3 months of study entry, No hx of hormonal agents, including dutasteride/finasteride within 6 months of study entry, No use of anticoagulation agents, except for the use of daily aspirin (81 to 325 mg)] self admin pills

## RADIATION

- 1. RTOG 0232** Steven **Frank** MD/Lois **Hamblin** RN 9/75 multi 586 **Activated 11/18/03** A Phase III Study Comparing Combined **External Beam** Radiation and Transperineal Interstitial Permanent **Brachytherapy** with Brachytherapy Alone for Selected Patients with Intermediate Risk Prostatic Carcinoma [T1c-T2b, if glea <7 PSA 10-20, if glea 7 PSA <10]
- 2. 2006-0038** Steven **Frank** MD/Lois **Hamblin** RN 172/200 **Activated 8/1/06** Transperineal interstitial permanent **brachytherapy alone** for selected patients with intermediate risk prostatic carcinoma [confirmed adenoca clinical stage T1c-T2bN0M0, CT or MRI lymph node eval required, intermediate risk is gleason <7 with PSA 10-15 OR gleason 7 with PSA <10, PSA prior to registration or hormones must be </= 15]

## HORMONE THERAPY PLUS PROSTATECTOMY

- 1. 2009-0322** *NCI-2009-01663* Christopher **Logothetis** MD/Donna Jones RN 23/66 IRB 6/11/09 activated 11/20/2009 A randomized, open-label, neoadjuvant prostate cancer trial of **abiraterone acetate plus LHRHa versus LHRHa alone** [adenoca via minimum of 6 core bx (no histology variants); Clinical stage T1c or T2 Gleason's 8-10 on initial bx, **OR** clinical stage T2b-T2c Gleason's grade > 7 & PSA > 10ng/ml; No evidence of mets; **antiandrogen** tx >4 wks prior to Cycle 1 Day 1] **3 month treatment**
- 2. 2009-0293** *NCT00924469* Christopher **Logothetis** MD/Robynne Ashe RN 14/15 multicenter 50/58 activated 10/9/09 **PCCTC c08-016** A Phase 2 Open-Label, Randomized, **Multi-center** Study of Neoadjuvant **Abiraterone Acetate (CB7630) Plus Leuprolide Acetate and Prednisone Versus Leuprolide Acetate Alone** in Men With Localized High Risk Prostate Cancer [At least 3 core bx + for prostate ca (min 6 core BL biopsies; **At least 1** of the following: **a)** PSA > 10 ng/ml; **b)** PSA velocity > 2 ng/ml/year (rise in PSA > 2 ng/ml in preceding 12 mo); **c)** Gleason score >= 7 (4+3); **d)** Gleason score 6 if either PSA >= 10 ng/ml or PSA velocity >= 2 ng/ml/year; **NO prior hormone therapy** including LHRH agonists/antagonists, orchiectomy, antiandrogens, ketoconazole, or estrogens (5-alpha reductase inhibitors allowed)] **6 month treatment**

## SYSTEMIC (chemo) THERAPY PLUS RADIATION

**2006-0684** *NCT00631527* Paul **Corn** MD/Donnah **Jones** RN 14/18 multi 15/18 activated 2/15/2008 **PCCTC c08-008** **Sunitinib** malate hormone ablation & **XRT** for high risk and locally advanced prostate cancer [clinical T2c, clinical or path T3 or T4 disease **OR** Gleason 8-10 disease **OR** PSA > 20ng/ml; **up to 8 wks of hormones** defined as LHRH or other medical castration prior to reg] (**accrual hold hx** 3/12 to 5/11/2010; 1/3/10 to 2/7/11)

## SYSTEMIC (chemo) THERAPY PLUS PROSTATECTOMY

- 1. 2009-0473** *NCT01163084* Christopher **Logothetis** MD/Donnah **Jones** RN 5/66 multi 4/80 activated 7/9/2010 **PCCTC c09-041** Preoperative **GDC-0449 & Androgen Ablation** Compared to **Androgen Ablation Alone** Followed by Radical Prostatectomy [adenoca via 6 core bx - minimum (no histology variants); T1c or T2 high-grade Gleason's 8-10 on bx; **OR** clinical stage T2b-T2c Gleason >= 7 **AND** PSA >10; Absence of major co-morbidity; radical prostatectomy candidate]
- 2. 2009-0135** *NCT01194271* Padmanee **Sharma** MD, PhD/ Carolyn **Harmon** RN 3/20 activated 9/1/2010 A Neoadjuvant Phase IIa Study of **Ipilimumab** {formerly known as MDX-010 (BMS-734016)} **Plus Hormone Ablation** in Men with Prostate Cancer Followed by Radical Prostatectomy [adeno, clinical stage T1-T3b (no small cell or sarcomatoid), No evidence of mets] 1 dose 22.5mg lupon ON STUDY; only ipi provided ~8 wks tx prior to surgery

## HORMONE THERAPY PLUS PROSTATECTOMY with SUSPECTED LYMPH NODES

**2011-0231** Amado **Zurita** MD/RN TBN 0/54 **NOT ACTIVATED** Pre-surgical Androgen Deprivation Therapy with or

without Axitinib in Previously Untreated Prostate Cancer Patients with Known or Suspected LymphNode Metastasis [adenoca of the prostate deemed resectable by urologist; at least 1 of the following: \*LN bx or LN dissection demonstrating LN mets \*non bulky (<5 cm) regional pelvic or distant lymphadenopathy on CT/MRI - LN bx required if <2.0cm or atypical \*primary gleason >=8 AND PSA >=25 \*T3 and gleason >=7 \* T4; less than 3 sites of non predominantly lytic bone mets; prior hormone up to 8 wks]

## **B. ANDROGEN DEPENDENT DISEASE**

### **RECURRENCE Biopsy Proven                      previously treated with radiotherapy**

**2009-0199** John Ward MD 6/20 multicenter 202 activated 9/3/2009 A multicenter clinical study of the **Sonablate® 500** (SB-500) for the treatment of locally recurrent prostate cancer with **HIFU** [organ confined recurrent cT1c & T2a only treated with EBRT (conventional, 3D conformal, or IMRT) >= 2 yrs prior; current biopsy proven local recurrence, **Age 40-85 yrs**]

### **BIOCHEMICAL FAILURE                      following any primary therapy**

**2009-0375** NCT00776594 Amado Zurita MD/Carolyn Harmon RN 6/10 multicenter 56/100 activated 7/27/2010 PCCTC c07-010 Randomized Phase II Trial of **Short-Course Androgen Deprivation Therapy +/- Bevacizumab** for PSA Recurrence of Prostate Cancer After Definitive Local Therapy [bx + prostate cancer any Gleason; Past tx with prostatectomy (no > pT1-3, N1, M0) salvage radiation ok, or primary radiation (XRT or brachy); PSA recurrence with PSAdt\* < 18 mo 3 PSA values required; no dz on scan; prior ADT allowed if 6 mos or less & testosterone recovered] **bevacizumab provided** LHRH analog is standard of care

### **BIOCHEMICAL FAILURE                      adding to GnRH monotherapy**

**2011-0275** NCT pending John Davis MD 0/5 A multicenter open label single arm phase 2 study of abiraterone acetate plus prednisone in subjects with advanced prostate cancer without radiographic evidence of metastatic disease [adenoca of prostate w/out neuroendocrine differentiation or small cell histology; current and continuous therapy with GnRH monotherapy for at least 6 mo before screening with serum testosterone of <50; rising PSA after local tx - PSA >=10 at screening or PSADT of <=6 mo w/baseline PSA of >=2]

### **SPECIAL ELIGIBILITY                      Previously on 2006-0220 placebo arm**

**2007-0131** Curtis Pettaway MD/Roosevelt Anderson 2/5 multi 30 Activated 12/12/2007 An Open Label Extension Study of the Effects of **Pomegranate** Extract on Rising PSA Levels [documented dz PD on placebo arm of 2006-0220]

## **DOCUMENTED METASTATIC DISEASE**

**2009-0378** NCT pnd Ana Aparicio MD/Pat Palmer RN 0/25 not active IRB approved 1/28/2010 A Phase II Study of **Ipilimumab PLUS Androgen Deprivation Therapy** in Castrate Sensitive Prostate Carcinoma [metastatic dz on bone scan and/or CT scan and/or MRI; on ADT are eligible as long as the time from LHRH analog initiation not greater than 1 mo AND total exposure time to LHRH analog will not exceed 8 mos; prior hormonal therapy (including bilateral orchiectomy) excluded, except 1) rec'd up to 4 mos hormonal ablation, as long as more than 1 yr has elapsed since dc; OR 2) rec'd up to 2 yrs of hormonal ablation, as long as more than 3 yrs have elapsed since its dc] **ipilimumab provide** LHRH analog is standard of care

## **C. HORMONE RESISTANT PROSTATE CANCER (AIPC HRPC CRPC)**

**LOCAL FAILURE ONLY** -no protocols at this time

### **NO DOCUMENTED METS                      PD by RISING PSA ONLY**

**2009-0754** NCT01046916 Paul Corn MD PhD/Victoria Brown RN 6/11 multi 7/42 activated 7/21/2010 PCCTC c10-064 A Phase 2 Multicenter Open-label Study Evaluating the Safety and Efficacy of **TAK-700** in Patients with Nonmetastatic Castration-resistant Prostate Cancer (CRPC) and a Rising PSA [PSA at least 1 wk apart, increasing over 2 serial consecutive measurements; BL PSA >= 2 ng/mL & PSADT <= 8 mos **OR** BL PSA >= 8 ng/mL **IF** PSADT is > 8 mos; **NO** prior aminoglutethimide or ketoconazole w/in 30 days prior to 1st dose of TAK; **NO** antiandrogen therapy w/in 4 wks for flutamide & 6 wks for others prior to 1st dose of TAK; **NO** prior chemo (adjuvant OK)]

### **ASYMPTOMATIC OR MILDLY SMPTOMATIC AND NO PRIOR THERAPY FOR METASTATIC DISEASE**

**2010-0921** NCT pnd Paul Corn/RN TBN 0/20 multi PCCTC NOT ACTIVE A Randomized, Double-Blind, **Placebo-Controlled**, Multicenter Phase II Study Investigating Two Doses of **EMD 525797** in Subjects with Asymptomatic or Mildly Symptomatic Metastatic Castrate-Resistant Prostate Cancer (mCRPC) [radiologic evidence AND PD of bone lesions with or w/o soft tissue lesions **within 2 weeks prior to randomization**, no chronic or ongoing treatment w opioids, no prednisone >10mg/day, no visceral mets]

### **NO PRIOR THERAPY FOR METASTATIC DISEASE**

1. **ON HOLD 2006-0840** NCT00477529 John **Araujo**/Helen **Phu** RN 31/45 multi 53 [29 pts 1st version] held 11/3/09 to 1/6/10 **PCCTC** A phase I/II trial of **ABI-008 (nab-docetaxel)** in patients with hormone refractory prostate cancer [evidence of PD either measurable dz w/ any PSA OR • Non-measurable dz w/ PSA  $\geq$  5 ng/ml]
2. **HOLD 2009-0261** NCT00527124 Amado **Zurita** MD/Deborah **Harris** RN 0/10 multicenter 104 **PCCTC** A randomized phase II trial of **AZD2171, docetaxel and prednisone compared to docetaxel and prednisone** in patients with metastatic hormone refractory prostate cancer [adenoca with mets; objective evidence of dz PD by imaging or rising PSA; PSA must be determined based on a rising trend with 2 successive elevations at a min interval of 1 wk; Pre-study imaging must be done **within 28 days of tx** hold hx 10/5/10-5/6/2011
3. **2011-0381** NCT pnd John **Araujo** MD PhD/RN TBN 0/20 multi 65 **NOT ACTIVATED** A phase 1/2 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 [adenocarcinoma PSA rising with a min PSA  $>$ 2; testosterone  $<$ 50; no hepatic or other soft tissue visceral or CNS mets; no prior TAK 700 or abiraterone or MDV3100 or TOK-001]

#### **PRIOR CHEMOTHERAPY ACCEPTED but NOT REQUIRED**

**2010-0070** NCT01254864 Christopher **Logothetis** MD/ Pauline **Dieringer** RN 26/180 activated 3/16/2011 **Maximal Androgen Depletion** Followed by Serial Randomization of **Maximal Androgen Ablation with Molecular Targeted Therapies** [adenoca prostate; mets on bone scan or lesions other than liver or visceral metastasis on CT, MRI; If LN only evidence of metastasis, must be  $\geq$ 2 cm; PSA PD according to PCWG2 or radiographic PD according to modified RECIST; Surgically or medically castrated, with testosterone of  $<$  50] abiraterone, dasatinib, sunitinib all provided

#### **PRIOR CHEMOTHERAPY REQUIRED**

1. **2008-0606** NCT00933426 Lance **Pagliari** MD/Pat **Palmer** RN 9/72 IRB 11/13/2008 **PCCTC c08-021 ACTIVATED** 8/4/2009 A modular phase I trial of **lenalidomide** and **paclitaxel** in metastatic castration-resistant prostate cancer with lymph-node dominant metastatic disease (AIPC) [PHASE I any mets; PHASE II only radiographic multiple ( $\geq$  2) or bulky ( $\geq$ 5cm diameter) LN mets with  $<$  2 bone (on bone scan) sites; No limit to prior chemo, however NONE in last 3 weeks; No prior thalidomide or lenalidomide; PD based 1of the following: a)PSA-PD= 2 consecutive increases in PSA (at least 1ng/mL) over 4 wks b) increase 25% of bidimensional dz OR 30% in max diameter OR new lesion c)worsening sx clearly attributable to disease]
2. **2010-0369** NCT pnd Randall **Millikan** MD PhD/RN TBN 0/39 **NOT ACTIVE IRB 10/14/10** A First-in-Man, Phase I Evaluation of A Single Cycle of **Prohibitin Targeting Peptide 1** in Patients with Castrate-Resistant Prostate Cancer and no Standard Treatment Options [**BMI obese** (i.e.  $>$  30 kg/m<sup>2</sup>) & in range of 30 to 45 kg/m<sup>2</sup>; Any histologic variant except pure small cell; PD w/in 3 mos; testosterone  $<$ 50 ng/dL; no standard options for therapy = dz PD (or intolerable AE) in context of a 2d line hormonal therapy (ketoconazole, abiraterone, low-dose dex, anti-androgens) **in addition to** docetaxel-based therapy, or two cytotoxic therapies, **at least 1 taxane**; Since there is no standard 2d-line therapy, pts are eligible **if they decline** to have additional cytotoxic therapy after failure of a taxane-based regimen; must be at least 4 wks from last tx prior to registration] **peptide provided**
3. **2011-0259** NCT pnd Paul **Corn** MD/RN TBN 0/15 multi 150 **NOT ACTIVE PCCTC** A Randomized Discontinuation Phase 2 Study of **AZD0530** as a Metastasis Inhibitor in Castrate Resistant Prostate Cancer (NCI 8446) [progression defined as clinical, radiographic, or PSA rise; adjuvant or neoadjuvant docetaxel not sufficient for inclusion]

#### **MUST HAVE DOCUMENTED BONE METASTASIS**

1. **2008-0510** NCT00831792 Paul **Corn** MD PhD/Pat **Palmer** RN 11/40 activated 4/7/2010 An observational study of **TKI 258** in castration resistant prostate cancer patients evaluating FGF signaling in the bone marrow of patients with infiltration by prostate cancer [adenoca w/ evidence for skeletal mets on scan; PD despite androgen deprivation - scan or PSA level of at least 5 ng/ml risen at least 2 occasions, at least 2 wks apart; corticosteroids may not be greater than 7.5 mg/day] HOLD hx 11/2/2010-5/2/2011
2. **2009-0886** NCT01091103 Christopher **Logothetis** MD/Robynne **Ashe** RN 57/62 **ACTIVATED** 2/17/2010 An Observational Study of Continuous Oral Dosing of a Novel Antiandrogen **MDV3100**, in Castration-Resistant Bone Metastatic Prostate Cancer Patients Evaluating the Tumor Micro-Environment [ Histologic or cytologic adenoca without neuroendocrine differentiation or small cell features; mets dz to the bone PD defined as **1 or more** of the following: : a) PSA min 3 rising PSA levels with interval  $\geq$  1 wk between each, value at Screening should be  $\geq$  2 ng/mL; b) Soft tissue defined by RECIST; c) Bone defined by 2 or more new lesions on bone scan (NOTE: prior antiandrogen must demonstrate PD following DC); **previous chemotherapy must have no more than 2 prior regimens at least 1 containing docetaxel**]
3. **2009-0529** NCT00940225 Razelle **Kurzrock**/Paul **Corn** MDs/Victoria **Brown** RN GU prostate NRE accrual 9/60 m/c 30/150 (MDACC all cohort accrual 100/300 all cohort multicenter 1300) (**recruiting other cancers in Experimental Therapeutics**) A randomized discontinuation study of **XL184** in subjects with advanced solid tumors [adeno ca; testosterone  $<$ 50; clear evidence of mets to bone on bone scans w/or w/o soft tissue mets; max 3 prior systemic cytotoxic chemo; 25% of accrual must have had docetaxel & cabazitaxel; objective PD - must have

occurred either during tx or w/in 6 mo of last taxane; PD defines as - mRECIST for soft tissue, worsened of bone scan 2 or more new lesions, development of an indication for XRT of bone w/a lesion outside field to follow]

## **DOCUMENTED BONE METASTASIS SYMPTOMATIC AND AMENABLE TO XRT**

**2009-0443** NCT00861614 Pam Sharma MD PhD/Pat Palmer RN 1/10 multi 800 activated 6/15/2010 A Randomized, Double-Blind, Phase 3 Trial Comparing **Ipilimumab vs. Placebo** Following **Radiotherapy** in Subjects with Castration Resistant Prostate Cancer That Have Received Prior Treatment with Docetaxel [testosterone <50; If applicable, DC'd 1st line anti-androgens 6 weeks prior to rand, or other anti-androgens at least 2 wks prior to rand; at least 1 prior regimen containing docetaxel, at least 2 cycles & c1 dose at least 75 mg/m<sup>2</sup>; PD by PSA min 1 wk intervals & 2.0 ng/mL starting value; PD per bone scan = 2 or more new lesions; PD per target/measurable lesions modified RECIST. Only lymph nodes >2 cm will be considered for disease PD]

## **WITH POSITIVE BONE MARROW ASPIRATE**

**2008-0395** NCT00872157 Randall Millikan MD PhD/Valerie Marcott RN 10/22 (need 12 EVALUABLE) activated 3/27/2009 (held 11/3 to 11/20/2009) -A Limited, First-in-Man, **Phase IB** Evaluation of **BMTP-11** in Patients with Castrate-Resistant Prostate Cancer with High-Volume Osseous Metastases and no Standard Treatment Options [Agree to trans-ilial bone bx AND have tumor (>single microscopic focus) demonstrated on a bx performed within 6 wks of reg; pts with BMbx as part of clinical care sufficient for eligibility allowed (no one will have repeat bx if done for clinical care only)] Hold hx 11/15/10 to 2/16/11

## **D. ANAPLASTIC PRESENTATION**

no trials at this time

## **RENAL CELL CARCINOMA**

### **A. NEWLY DIAGNOSED NON METASTATIC NEOADJUVANT**

**2010-0072** Christopher Wood MD/Nancy Ainslie RN 1/24 activated 2/22/2011 A Phase II Clinical Trial Examining the Impact Of Neoadjuvant **Axitinib** On Primary Tumor Response In Patients With Locally Advanced Clear Cell Renal Cell Carcinoma [Locally advanced RCC w/out metastatic dz; absence of adjacent organ invasion or retroperitoneal adenopathy (cT2-T3b, N0, M0); **predominant clear cell histology** on pre-enrollment biopsy; candidate for curative radical nephrectomy]

### **ADJUVANT**

**2010-0618** Christopher Wood MD/RN TBN 0/10 mult 1500 NOT ACTIVATED IRB 12/15/2010 A randomized, **double-blind, placebo-controlled** phase III study to evaluate the efficacy and safety of **pazopanib** as adjuvant therapy for subjects with localized or locally advanced RCC **following nephrectomy** [clear cell or predominant clear cell; non metastatic (M0); pT2, G3 or G4 N0 or pT3 Gany N0 or pTany Gany N1; radical or partial nephrectomy recovered; randomize within 12 of nephrectomy] placebo/pazopanib provided

### **B. METASTATIC DISEASE FRONT LINE - NO PRIOR SYSTEMIC TREATMENT CLEAR CELL CARCINOMA aka CONVENTIONAL CELL TYPE PRIMARY INTACT**

**2007-0511** NCT00715442 Eric Jonasch MD/RN Valerie Marcott 45/50 ACTIVATED 6/24/08 Phase II Non-Randomized **Pre-Surgical** Study Evaluating **Sunitinib** in Patients With Metastatic Renal Cell Carcinoma (RCC) Who Are Eligible for **Cytoreductive Nephrectomy** [measurable dz other than primary; no organ allograft] hold hx 4/7-5/11/2009]

### **POOR RISK CLEAR CELL CARCINOMA**

**2011-0358** NCTpnd Nizar Tannir MD/tbn RN 0/90 NOT ACTIVATED A randomized phase 2 trial of **pazopanib versus temsirolimus** in poor risk clear cell renal cell carcinoma [metastatic or locally advanced RCC **major clear cell component**; poor risk 3 or more of the following: ECOG 2, anemia, elevated LDH, hypercalcemia, dx to registration <1 yr & >1 met organ site]

### **NON CLEAR CELL CARCINOMA OR UNRESTRICTED HISTOLOGY**

**2009-0628** NCT01185366 Nizar Tannir MD/Lisa Smith RN 10/108 activated 8/18/2010 Randomized Phase II Trial of **Everolimus versus Sunitinib** Therapy in Patients with Advanced Non-clear Cell Renal Cell Carcinoma [advanced **non-clear cell RCC subtypes**; at least 1 measurable site; fasting serum cholesterol <=300 mg/dL or <=7.75 mmol/L AND fasting triglycerides <=2.5 ULN; No prior adjuvant tx; no chronic corticosteroids]

### **C. METASTATIC DISEASE WITH OR WITHOUT PRIOR THERAPY CLEAR CELL CARCINOMA/CONVENTIONAL CELL TYPE**

**2010-0085** NCT01217931 Nizar Tannir MD/Lisa Smith RN 17/240 ACTIVATED IRB 1/19/2011 **Sequential two agent** assessmnt in renal cell carcinoma therapy: the START trail [confirmed metastatic RCC **w/clear cell component**; [OK prior

immunotherapy, such as cytokines or vaccines; **NO prior targeted therapy** (anti-VEGF agents or mTOR inhibitors) including adjuvant therapy; **NO** prior chemotherapy] **everolimus provided**. At PD may randomized to a salvage combo. ARM possibility: **pazopanib** - bevacizumab OR everolimus; **everolimus** - bevacizumab OR pazopanib; **bevacizumab** - pazopanib OR everolimus

## **NON CLEAR CELL CARCINOMA OR UNRESTRICTED HISTOLOGY**

**2006-0433** NCT00496587 Lance **Pagliari** MD Robynne **Ashe** RN 29/40 Activated 7/2/07 Phase II safety & efficacy study of **capecitabine gemcitabine and bevacizumab** in combination for patients with metastatic or unresectable **sarcomatoid renal cell** carcinoma [**any prior immunotherapy but NO cytotoxic chemo**; histological minimum of 1 focus of recognized RCC and at least 10% sarcomatoid feature]

## **PHASE I STRATEGY**

**2009-0037** NCT01122615 Nizar **Tannir** MD/Lisa **Smith** RN 6/60 active 5/10/2010 Phase I Trial of **Sunitinib plus Temsirolimus** in Patients with Metastatic Renal Cell Cancer [confirmed mRCC **any histological subtype** with evaluable disease, **NO** uncontrolled hypertn]

### **D. METASTATIC DISEASE MUST HAVE PRIOR THERAPY**

**2010-0247** NCI 8727 Eric **Jonasch** MD/Valerie **Marcott** RN 13/60 and 9/60 on treatment activated 1/27/2011 A randomized phase 2 study of **MK 2206** comparison with **everolimus** in refractory renal cell carcinoma [**all histologies permitted**; patient should have undergone nephrectomy; measurable dz; **MUST** have rec'd & progressed on anti VEGF therapy (bev, sorafenib, sunitinib, or pazopanib); may have rec'd up to 2 prior agents; known brain mets excluded; hgb A1c <8%]

### **E. METASTASECTOMY**

**2009-0038** NCT00918775 Eric **Jonasch** MD/Deborah **Harris** RN 12/56 activated 6/9/2009 A Phase II **Metastasectomy** Study for Patients with Renal Cell Carcinoma [clinical reasons for surgical resection of tumor. a)fully resectable dz: lesions accessible by surgeon during no more than 2 separate surgical sessions, & expected to be rendered NED b) undergoing noncurative procedure for relief of symptoms or for management of threatening lesions]

### **F. VON HIPPEL LINDAU SYNDROME**

**2010-0650** NCT01266070 **Eric Jonasch** MD TBN RN **0/25 NOT ACTIVE** A Pilot Trial of **TKI 258 (dovitinib)** in Von Hippel-Lindau Syndrome[genetically confirmed VHL dz; At least 1 measurable hemangioblastoma undergoing surveillance **and** not at immediate need of intervention; Bx not required if + genetic test; Brain: asymptomatic hemangioblastoma, > 0.5 cm; Spine: asymptomatic hemangioblastoma, > 0.5 cm; Renal: solid mass suspicious for RCC >=1 cm or cystic mass >=1 cm; Pancreas: solid mass >=1cm and < 3 cm suspicious for neuroendocrine tumor; Eye: asymptomatic peripapillary and/or macular hemangioblastoma, any size; Adrenal: Pheochromocytoma greater than 1cm in size; Previously radiated lesions may not be considered as target unless they demonstrate unequivocal evidence of growth; Major surgery, chemotherapy or radiation therapy completed > 4 weeks prior to starting the study treatment; Age >= 18 years]

## **UROTHELIAL**

### **A. At Risk for Urothelial Cancer**

**2007-0163** H. Barton Grossman MD/Mary McCabe 267/500 multi 2000 Active 3/31/08 **Screening** for Bladder Cancer [Men 60+ current smokers or hx of 20 pack/yr, ≥ 30 pack/yr hx who within 10 yr, or 40 pack/yr hx regardless of quit date. Men are ineligible if they have histories of urothelial cancer]

### **B. Intravesical Administration Failed prior therapy**

**SWOGS0337** Ashish Kamat MD/Alice Abraham RN 3/50 multi 340 IRB 9/11/2008 held 5/12/2009 to Sept A Phase III Blinded Study of Immediate Post-TURBT Instillation of **Gemcitabine Versus Saline** in Patients with Newly Diagnosed or Occasionally Recurring Grade I/II Superficial Bladder Cancer [new/recurrent Grade 1 or 2, Ta or T1 TCC; patient must TURBT within 10 days after rand & tx given within 3 hrs of TURBT; no prior bladder cancer for >= 9 months before the index tumor resection; no more than 2 recurrences in last 3 yrs (grade 1 or 2, Stage Ta or T1) no previous TIS, Grade 3 Stage >= T2]

**2009-0938** Colin Dinney MD/RN TBN 1/9 multicenter activated 4/20/2011 Phase 1B **Intravesical Administration** of **SCH 721015** in Patients with Transitional Cell Carcinoma of the Bladder [Histologically proven recurrent urothelial carcinoma Tis, Ta; recurrent T1 dz who do not want cystectomy; must have failed at least 2 prior courses of BCG w/ or w/out IFN; at least 3 mos since last intravesical tx]

### **C. Eligible for cystectomy**

#### **Post Operative Management**

**2009-0244** Ashish Kamat MD/ TBN RN 20/28 multicenter 280 activated 11/2/2009 A phase 4, multicenter, double-blind, placebo-controlled, parallel study of **alvimopan** for the management of **postoperative ileus** in subjects undergoing radical

cystectomy [18 yrs; American Society of Anesthesiologists Physical Status Score I-III; scheduled radical cystectomy; postop pain management with IV opioid PCA; NG tube removed before 1st postop dose of study med on the morning of POD 1]

### High Risk Neoadjuvant

no trials at this time

### Recurrent or Extensive Disease Requiring Cystectomy

**2007-0704** NCT00749892 Arlene **Siefker-Radtke** MD/Wanda **Jacobs** RN 30/42 Activated 6/10/08 A Phase II Exploratory Study of Pre-Operative Treatment with **Erlotinib** (Tarceva) in Muscle Invasive or Recurrent Transitional Cell Carcinoma Requiring Cystectomy [diagnosis of surgically resectable urothelial cancer including pts requiring cystectomy, pts with recurrent or extensive superficial (cTa-T1N0M0), CIS (carcinoma in situ), or muscle invasive (cT2-3aN0M0), whose tumor could not be completely removed at transurethral resection. Pts refusing cytoreductive chemotherapy may be considered eligible.

### D. Adjuvant Therapy for High Risk Urothelial Cancer

**2011-0xxx** NCT pending Arlene **Siefker-Radtke** MD/TBN RN x/x **NOT ACTIVATED** A randomized study evaluating **DN24-02** as adjuvant therapy in subjects with high risk HER2+ urothelial carcinoma

### E. Metastatic or Unresectable Urothelial Cancer

#### No Prior Systemic Therapy

**2005-0839** NCT 00478361 Lance **Pagliari** MD/Deborah **Harris** RN 30/72 *multi* **NCI #7341** 20/72 **CCOP** Activated 4/24/07 A phase II study of **gemcitabine, paclitaxel, and doxorubicin**, with same day pegfilgrastim for the treatment of patients with metastatic transitional cell carcinoma **AND** renal insufficiency [confirmed metastatic or unresectable TCC. Mixed TCC or variant histology (small cell, squamous, adenocarcinoma, sarcoma) are permitted if present in < 50% of the biopsy specimen. Any prior intravesicular chemotherapy is allowed. Measurable disease, may include radiographic detection of metastases in lymph nodes (>= 1.5 cm), liver or lung (>= 1.0 cm), or pelvic mass palpable on examination under anesthesia. Creatinine clearance < 60 ml/min ] **commercial drugs**

#### Must have Prior Systemic Therapy

**2006-0014** NCT00479128 Arlene **Siefker-Radtke** MD/Wanda **Jacobs** RN 50/80 Activated 9/28/2006 **Phase I** two dimensional dose finding study of **bortezomib** in combination with **gemcitabine/doxorubicin**, followed by a phase II extension to assess the efficacy of this combination in metastatic, surgically unresectable urothelial cancer [For 2nd stage of **phase I**, all must have histologic metastatic or locally unresectable TCC; minor components (<50% overall) of variant histology or aggressive phenotypes are acceptable; however, **dominant** atypical histologies are not eligible, must have had **at least 1 prior therapy**; any number of prior regimens regardless of what they contained ok; advanced dz with measurable lesions] all IV: push bortezomid, 30 min gem, 1hr or 24-36 CI dox

### F. Localized Prophyllaxis

**2007-0933** Seungtaek Choi MD/Lois Hamblin RN 5/30 Activated 7/21/2008 Prophylactic **Cranial Irradiation (PCI)** for patients with small cell carcinoma of the urothelium

### G. Rare Urothelial Tumors

#### Adenocarcinoma or Urachal Remnant or Small Cell Carcinoma

no trials at this time

## TRANSLATIONAL and INFORMATION RESEARCH

### Non Tumor or Normal

**LAB07-0198** Jeri **Kim** MD/Trish Jensen-Loewe 26/9999 Activated 6/8/07 **Normal Donor Tissue Bank**

### All Tumor Types

**ID99-417** Christopher **Logothetis** MD/Pauline **Dieringer** RN 6/10 Activated 5/3/00 Screening **Phage Display** Random Peptide Libraries in Humans [special ICU patients]

**LAB02-152** Jeri **Kim** MD/Trish **Jensen-Loewe** 703/9999 Activated 5/30/02 Prospective **Tissue Bank** for Patients With or Suspected to Have Genitourinary Malignancies [all GU patients scheduled for routine diagnostic tissue]

**2005-0027** Padmanee **Sharma** MD/Trish Jensen-Loewe 204/450 Activated 6/7/05 Laboratory **immunological studies** on blood and tumor tissues from patients with genitourinary cancers [90 cc of blood drawn]

### Germ Cell Tumors

**LAB06-0017** ShiMing **Tu** MD/Trish **Jensen-Loewe** 6/60 Activated 10/23/06 Clinical features and biological implications

of the **atypical seminoma**

#### **Prostate**

**LAB02-490** Curtis **Pettaway** MD/Pam Roberson & Jackie Frost 5,231/12,700 Activated 02/24/03

Prostate **Serum/Tissue Bank** in Underserved Minority Populations [minority patients]

**LAB05-0261** Jeri **Kim** MD/Trish **Jensen-Loewe** 114/800 Activated 8/22/2006 Detection of Circulating Tumor Cells Expressing **MDA-BF-1** in the Blood of Patients with Prostate Cancer and Bone Metastasis: Correlation with disease Progression in Bone and Response to Therapy

**2007-0302** Deborah **Kuban** MD Lydia Madsen RN 710/1448 Activated 11/14/07 A comprehensive **multimodality QOL** for prostate cancer [clinical T1c to T3b adenocarcinoma who are undergoing radical retropubic or robotic prostatectomy, photon XRT or XRT + ADT, proton radiation, radioisotopic implant, cryotherapy, or active surveillance]

#### **Renal**

**LAB02-176** Christopher **Wood** MD/Amrita Goswami 956/1000 Activation 05/28/02 Identifying novel alterations in **gene and protein expression** associated with the metastatic phenotype and response to systemic therapy in metastatic and locally advanced renal cell carcinoma

**2005-0426** Surena **Matin** MD/Amrita Goswami 247/300 Activated 10/20/05 **Expectant Management** of Localized Renal Tumors: Natural History and Quality of Life [any MDA pt undergoing watchful waiting of localized tumor]

**LAB11-0190** Surena **Matin** MD x/x **NOT ACTIVATED** The use of stimulated whole **saliva** as a **diagnostic test** for the detection of renal cell carcinoma [>4cm suspected to be consistent with stage I II or III RCC; surgically resectable dz]

#### **Urothelial**

**LAB05-0326** Ashish **Kamat** MD/Roosevelt Anderson 149/150 Activated 6/3/05 **Markers of Response** to Intravesical Bladder Cancer Therapy [non muscle invasive TCC with intact bladder Ta, T1 or TIS grade 1, 2, or 3]

**REFER NEW PATIENTS to the GU Business Center 1-866-363-1332 OR  
CLINICAL TRIAL INFORMATION LINE 713-563-1602** Cherie Perez RN CCRP

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