

CURRENT UW-SCCA GU CLINICAL TRIALS

Neoadjuvant	Non-Met	Glea	Stage		PSA	Study Design	Type	Route	Notes
Sorafenib ⁶	X	8-10	T2b - T3		≥ 20	Open-label of Sorafenib prior to prostatectomy	Molecular targeted therapy	PO	Study open: Must be Stage T2b or T3 OR PSA ≥ 20 OR Overall Gleason 8-10; RP planned as tx; no prior PCa
TAPS ⁵	X	7-10	T1 - 3		< 40	Open-label rand: Zoladex + Casodex +	neoadjuvant AS	IM-PO	Study open: 3 arms; no cardiac hx. T>280; RTC for blood c
Biochemical Relapse PCa	Met	Non-Met	Asx only	Prior Chemo OK	Min PSA	Study Design	Type	Route	Notes
Early Taxotere		X			0.2	Phase II of early use of docetaxel in patients with biochemical relapse after primary tx for PCa	chemo	IV	Open approximately February 2008: Nadir serum PSA after initiation of ADT following primary tx > 0.2 and must be confirm by 2 or more PSAs that are the same or higher.
TARP ⁵ (Avo108943)		X	X		2.0 - 20.0	Phase 4 randomized 1:1 caso + dutasteride vs caso + placebo, rising PSA on LHRH	LHRH agonist, antiandrogen, & SARI		Study open: Stable cardiac OK, no dutasteride or finasteride within 6 mos prior
IAS ³		X				Phase II of intermittent androgen suppression	LHRH agonist, & antiandrogen	IV and PO	Study open and enrolling
AVIAS ³		X	X		2.0 - 6.0	Intermittent androgen suppression with dutasteride or matching placebo	LHRH agonist, antiandrogen, & SARI	PO and IM	Study open: No prior AS treatment, must have failed curative therapy

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Non-metastatic and metastatic HRPC	Met	Non-Met	Asx only	Prior Chemo OK	Bisph. OK	Min PSA	Study Design	Type	Route	Notes
Mitoxantrone + IMC-A12 or IMC-1121B	X			X	X	2.0	Phase II Randomized Open-Label	Chemo + IGF-1R or VEGFR-2 monoclonal antibodies	IV	Study open and enrolling: must have failed docetaxel, no other prior chemos allowed
AMG 102 + Mitoxantrone ³	X			X	X	2.0	Phase 1b/2 Open Label	HGF monoclonal antibody	IV	Study open, Dosing Cohort closed. Due to re-open March 09: must have failed taxane-based therapy, no more than one prior chemo.
Cougar 301 Abiraterone ³	X			X	X	NA	Phase III Randomized, Placebo-Controlled	Adrenal androgen inhibitor	PO	Study opening January 30, 2009 : must have failed docetaxel, no more than 2 prior chemo regimens
Astra Zeneca ZD4054 ³		X	X			1.2 - 5.0	Phase III, Randomized, Double-Blind, Placebo-Controlled	ETA receptor antagonist	PO	Study open: PSA must be ≥1.2 in patients with RP and ≥ 5.0 in all other patients
Taxotere +/- GM-CSF ¹	X				X	5.0	Phase II of Intermittent Chemo +/- Maintenance GM-CSF	chemo immunotox	IV subcut	Study open: Late enrollment option for patients who have received ≤3 cycles of docetaxel, if docetaxel administered q3wk schedule and each dose was bet. 6--75 mg/m2.
Nerviano PHA-739358 ¹	X			X	X	NA	Phase II open-label 2nd-line for docetaxel failures	Aurora Kinase Inhibitor	IV	Study open. Must have failed docetaxel. Pts randomized to either 24-hr infusion or 6-hr infusion.
Hollis-Eden HE3235 ⁷	X			X		2.0	Phase I/II Open-label 2nd line for docetaxel failure	Androgen-receptor antagonist	PO	Study open: Must have failed at least 1 taxane regimen, progressive disease despite androgen therapy. Serum testosterone < 50 ng/mL Enrolls in cohorts so check with coordinator.
OGX-427 ⁷	X			X	X	NA	Phase I, open-label OGX-427	Antisense Oligonucleotide to Hsp27	IV	Study open. Must have Prostate, Bladder, Breast, Lung, or Ovarian cancer. Enrolls in cohorts so check with coordinator about slot availability
MDV3100 ¹	X	X		X		2.0	Phase I, open-label MDV3100	Androgen-receptor antagonist	PO	Study open. Enrolls in cohorts so check with coordinator about slot availability
MDX-010 ⁷	X				X	5.0	Phase II open-label of MDX-010	CTLA monoclonal antibody	IV	Study open. Dose expansion cohort now allows for prior chemo. Must be candidate to receive xrt to single bone met
Novartis MCS-110 ¹	X		X				Phase I/II open label study of MCS-110	Murine monoclonal anti-m-csf antibody	IV	Study opening early February 2009. Enrolls in cohorts so check with coordinator regarding slot availability
Duke Microarray	X					2 rises above nadir	Phase II study to see micro-array based response can predict response to chemo	Docetaxel	IV	At IRB. Study open early February 2009
SWOG Docetaxel +/- Atrasentan ⁴	X		X		X	5.0	Randomized, double-blind phase III study of Docetaxel +/- Atrasentan	chemo targeted	IV PO	Study open. Must have positive bone scan

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or visit the website: http://www.medical.washington.edu/studies/specific_list.asp and select "prostate cancer"

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Non-Treatment Imaging	Met	Non-Met	Hxt	XRT	Prior Chemo OK	PSA	Study Design	Type	Route	Notes
11C-acetate PET ⁵ (acetate PETs)		X	X	X		≥0.40*	Non-tx, non-intervention: PET scan prior to RP or LN staging	Imaging		ENROLLMENT ON HOLD PENDING MODS; High risk of LN mets; *No min PSA for tx-naive, but >4 post-RP or pre-AS or pre-chemo AT (1-20); 4-6 wk anti-andro was not, biph start >4 wk prior; 2 scans (BL & 6-12 wk later); Tue-Wed. Thu afternoons only.
Mets PET ⁵ (Evan's acetate PET)	≥3 bone		OK	OK >4 wk prior		na	Non-tx, non-intervention: PET scan, survey, diary	Imaging		
FES PET ⁵	X		OK	OK	X	na	Non-tx, non-intervention: PET scan only	Imaging		
Stage IV TCC of Urothelium	Met	Non-Met	Asx Only	Prior Chemo OK	Study Design	Type	Route	Notes		
Gem/Cis +/- Cetuximab	X			X (prior neoadj or adj chemo OK)	Phase II randomized open-label	Chemo +/- EGFR monoclonal antibody		Study open February 2009: must have T4bN0 or any T, N2-3 disease, no prior EGFR tx		
Zactima ⁷	X			X	Phase II randomized of docetaxel +/- zactima	VEGFR small molecule inhibitor	PO	Study open and enrolling. Must have received chemo with a platinum salt. 1-3 prior systemic chemo or investigational treatment regimens. No prior treatment with a taxane or VEGF-axis agent		

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