

CURRENT UW-SCCA GU CLINICAL TRIALS

Neoadjuvant	Non-Met	Glea	Stage	PSA	Study Design	Type	Route	Notes	
ADT + IMC-A12 ⁵	X	8-10	T2c - T3	> 20	Open-label: Caso+Zola+IMC-A12 for 3 months	Anti- IGF-1R Monoclonal antibody	PO-IM-IV	Study open, must be Gleason 8-10 OR T2c OR T3, OR PSA >20, OR Kattan Recurrence > 50%. Pre-treatment biopsy required. No diabetes; infusions on Wednesdays only	
SAHA ⁵	X	any	T2-T3	≥~20	Open-label of Zoladex+caso+ vorinostat for 2 months	histone deacetylase inhibitor	PO-IM	study open, PCA in ≥3 bx cores, one with >30% tumor; no uncontrolled cardiac or other significant illness	
Sorafenib ⁶	X	8-10	T2b - T3	≥ 20	Open-label of Sorafenib prior to prostatectomy for 6 wks	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 ± Avodart ± ketoconazole for 3 mon.	neoadjuvant AS	IM-PO	Study open: 3 arms; no cardiac hx, T>280; RTC for blood q 4wk for 3 mos pre-surg; must stop statins if arm 3	
<i>Neoadjuvant Abiraterone</i>	<i>X</i>	<i>7-10</i>	<i>T1-T3</i>		<i>At least 3 biopsy cores positive.</i>	<i>neoadjuvant AS</i>	<i>PO/IM</i>	<i>Anticipate study open in July, 2009. 3 months of abiraterone/LHRH vs. LHRH followed by 3 months of abiraterone/LHRH then prostatectomy</i>	
Biochemical Relapse PCa	Met	Non-Met	Asx only	Prior Chemo OK	Min PSA	Study Design	Type	Route	Notes
Early Taxotere ²		X			0.2	Phase II of early use of docetaxel in patients with biochemical relapse after primary tx for PCa	chemo	IV	Opened May 15, 2009: 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, & 5ARI		Study open: Stable cardiac OK, no dutasteride or finasteride within 6 mos prior
IAS ²		X				Phase II of intermittent androgen suppression	LHRH agonist, & antiandrogen	IV and PO	Study open and enrolling
AVIAS ²		X	X		2.0 - 6.0	Intermittent androgen suppression with dutasteride or matching placebo	LHRH agonist, antiandrogen, & 5ARI	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 ⁷	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, in phase 2 portion of the study; must have failed taxane-based therapy, no more than one prior chemo.
<i>Cougar 302 Abiraterone³</i>	<i>X</i>					<i>NA</i>	<i>Phase III Randomized, Placebo-Controlled (1:1)</i>	<i>Adrenal androgen inhibitor</i>	<i>PO</i>	<i>Study startup in process; expect opening ~June 19, '09 ; mild symptoms or asymptomatic</i>
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 immunotx	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/m ² .
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.

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and metastatic	Met	Non-Met	only	Chemo	Bisph. OK	Min PSA	Study Design	Type	Route	Notes
Docetaxel--Duke Microarray ³	X					2 rises above nadir	Phase II study to see micro- array based response can predict response to chemo	Docetaxel	IV	Study open, requires bone biopsy at UWMC radiology
Docetaxel +/- Dasatinib ³	X				X	rising and ≥2 ng/mL	Phase III randomized doubleblind, placebo controlled all pts, receive docetaxel + pred	SRC tyrosine kinase inhibitor	PO	study pending, target startup ~8/1/09. No sig CV dis., EF >40%
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
Non-Treatment Imaging	Met	Non-Met	Hxt	XRT	Prior Chemo OK	PSA	Study Design	Type		Notes
Mets PET ⁵ (Evan's acetate PET)	≥3 bone		OK	OK >4 wk prior		na	Non-tx, non-intervention: PET scan, survey, diary	Imaging		pre-AS or pre-chemo AI (T<20), 4-6 wk anti-andro washout; bisph start >4 wk prior; 2 scans (BL & 6-12 wk later); Tue- Wed-Thu afternoons only
Stage IV TCC of Urothelium		Met	Non- Met	Asx Only	Prior Chemo OK		Study Design	Type	Route	Notes
Gem/Cis +/- Cetuximab ⁷		X			X (prior neoadj or adj chemo OK)		Phase II randomized open-label	Chemo +/- EGFR monoclonal antibody		Study enrollment currently on hold pending protocol revision, contact coordinator; 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 VEFG-axis agent

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