

CURRENT UW-SCCA GU CLINICAL TRIALS

| Neoadjuvant | Non-Met | Glea | | Stage | PSA | Study Design | Type | Route | Notes | |
|--|----------|-------------|--|----------------------|----------------|---|--|------------------------------------|---|--|
| PASS | X | | | T1 - 2 | | Active Surveillance for patients with localized disease | Active Surveillance | N/A | Study open: patients must have elected active surveillance, must visit Seattle Q6 months, repeat bx required at intervals | |
| 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; RTC for blood q 4wk for 3 mos pre-surg; must stop statins if arm 3 | |
| Diet Study ⁸ | X | 3+3, 3+4 | | T1-T2 | < 20 | Randomized to 6-week dietary intervention (caloric restriction diet with nutritionist) or standard diet | | n/a | Study open. BMI > 25, no diabetes. 2 fasting visits to FHCRC. Diet group -- weekly nutritionist appts at FHCRC (or by phone) | |
| 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 | |
| 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 insulin dependent diabetes | |
| 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 therapy | |
| <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 September, 2009. 3 mon of abiraterone/LHRH vs. LHRH followed by 3 mon of abiraterone/LHRH then prostatectomy</i> | |
| RTOG 0534 - radiotherapy ¹⁰ | X | ≤ 8 | | pT3No/NX or pT2No/NX | ≥0.1 and < 2.0 | Phase III trial of short term androgen dep. w pelvic lymph node or prostate bed only radiotherapy | Salvage XRT | IM | rising PSA following radical prostatectomy; ≥ 6 wks prostatectomy, perf. Status 0-1; NO androgen deprivation after prostatectomy and /or > 6 months prior to prostatectomy : pts randomized to Pros. Bed RT alone, or Prost Bed RT + HDT, or pelvic lymph node + Pros bed RT+ HDT | |
| Biochemical Relapse PCa | Met | Non-Met | | Asx only | Prior Chemo OK | Min PSA | Study Design | Type | Route | Notes |
| 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 |

For more information please contact:

1Peggy Pitzel, RN Phone: (206) 288-2171 Pager: (206) 995-7592

3Teresa Gambol Phone: (206) 288-6452 Pager: (206) 541-1547

5Sara Teller Phone: (206) 598-0854

7 Deb Chielens Phone:(206) 288-1189 Pager: (206) 344-9133

9 Laura Baker phone: (206) 1187 Pager: (206) 540-0377

2 Alma MacAraeg Phone: (206) 288-1349

4SWOG Coordinator Phone: (206) 288-1231

6 Debby Bernard (206) 667-4458

8 Carolyn Bain (206) 667-7858

10-Robyn Haaf - (206) 667-5974 **or Marge Koe** (206) 598-4127

or visit the website: www.depts.washington.edu/guoncrs/ click on the Clinical Trials tab and then click on For physicians and healthcare providers link

CURRENT UW-SCCA GU CLINICAL TRIALS

| Non-metastatic and metastatic HRPC | Met | Non-Met | First line/Second line/etc | Asx only | Prior Chemo OK | Bisph. OK | Min PSA | Study Design | Type | Route | Notes |
|--|-----|---------|----------------------------|----------|----------------|-----------|-----------|---|---|-----------|---|
| Mitoxantrone + IMC-A12 or IMC-1121B ⁹ | X | | 2nd line and beyond | | X | X | 2.0 | Phase II Randomized Open-Label | Chemo + IGF-1R or VEGFR-2 monoclonal antibodies | IV | Study open and enrolling, only ~10 slots left, please call coordinator as soon as possible to ensure we reserve a slot for your pt: must have failed docetaxel, no other prior chemos allowed |
| AMG 102 + Mitoxantrone ³ | X | | 2nd line and beyond | | 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. |
| Cougar 302 Abiraterone ³ | X | | 1st line chemo naïve | | | | NA | Phase III Randomized, Placebo-Controlled (1:1) | Adrenal androgen inhibitor | PO | Open to enrollment; mild symptoms or asymptomatic, no pain meds, no opiates, no radiation |
| 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 | | 1st line chemo naïve | | | 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 | | 2nd line and beyond | | 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. |
| OGX-427 ⁷ | X | | 2nd line and beyond | | 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, check with coordinator about slot availability |
| Hollis-Eden HE3235 ⁷ | X | | 2nd line and beyond | | 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. |

For more information please contact:

¹Peggy Pitzel, RN Phone: (206) 288-2171 Pager: (206) 995-7592

³Teresa Gambol Phone: (206) 288-6452 Pager: (206) 541-1547

⁵Sara Teller Phone: (206) 598-0854

⁷Deb Chielens Phone: (206) 288-1189 Pager: (206) 344-9133

⁹Laura Baker phone: (206) 1187 Pager: (206) 540-0377

or visit the website: www.depts.washington.edu/guoncrs/ click on the Clinical Trials tab and then click on For physicians and healthcare providers link

²Alma MacAraeg Phone: (206) 288-1349

⁴SWOG Coordinator Phone: (206) 288-1231

⁶Debby Bernard (206) 667-4458

⁸Carolyn Bain (206) 667-7858

¹⁰Robyn Haaf - (206) 667-5974 or Marge Koe (206) 598-4127

CURRENT UW-SCCA GU CLINICAL TRIALS

| Non-metastatic and metastatic HRPC | Met | Non-Met | First line/Seco nd line/etc | Asx only | Prior Chemo OK | Bisph. OK | Min PSA | Study Design | Type | Route | Notes |
|---|---------|---------|-----------------------------|----------|----------------|----------------------------------|----------------------------|---|--------------------------------------|-----------|--|
| <i>Docetaxel--Duke Microarray³</i> | X | | 1st line chemo naïve | | | | 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 |
| <i>Docetaxel +/- Dasatinib³</i> | X | | <i>1st line chemo naïve</i> | | | X | <i>rising and ≥2 ng/mL</i> | <i>Phase III randomized doubleblind, placebo controlled all pts, receive docetaxel + pred</i> | <i>SRC tyrosine kinase inhibitor</i> | <i>PO</i> | <i>study pending, target startup ~8/21/09. No sig CV dis., EF >40%</i> |
| SWOG Docetaxel +/- Atrasentan ⁴ | X | | 1st line chemo naïve | 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 |
| <i>ACRIN Na+18F PET</i> | | | | | | | <i>na</i> | <i>Non-tx, non-intervention: PET scan, survey, diary</i> | <i>Imaging</i> | | <i>Must be enrolled in Duke Nilutimide vs Dasatinib treatment trial: Due to open 9/09</i> |
| 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 VEGF-axis agent |

For more information please contact:

1Peggy Pitzel, RN Phone: (206) 288-2171 Pager: (206) 995-7592

2 Alma MacAraeg Phone: (206) 288-1349

3Teresa Gambol Phone: (206) 288-6452 Pager: (206) 541-1547

4SWOG Coordinator Phone: (206) 288-1231

5Sara Teller Phone: (206) 598-0854

6 Debby Bernard (206) 667-4458

7 Deb Chielens Phone:(206) 288-1189 Pager: (206) 344-9133

8 Carolyn Bain (206) 667-7858

9 Laura Baker phone: (206) 1187 Pager: (206) 540-0377

10-Robyn Haaf - (206) 667-5974 or Marge Koe (206) 598-4127

or visit the website: www.depts.washington.edu/guoncrs/ click on the Clinical Trials tab and then click on For physicians and healthcare providers link