

# Front Range Cancer Specialists

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## **Active Study List November 2009**

**This list is to be used only to identify possible study patients and not as a screening tool as eligibility requirements change frequently. For current protocol status & patient eligibility questions, call the research team at the PVHS Cancer Center:**

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**POUDRE VALLEY  
HEALTH SYSTEM**

Key:

N = NCCTG  
C = CALGB  
S = SWOG  
E = ECOG  
R = RTOG  
G = GOG

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## Phase I

### **C4-08-001 (Cylene Pharmaceuticals) A Phase I, Multi-Center, Open-Label, Dose-Escalation, Safety, Pharmacokinetic, and Pharmacodynamic Study of CX-4945 Administered Orally to Patients with Advanced Solid Tumors, Castleman's Disease or Multiple Myeloma**

Study Activated: 12/1/08

Accrual: 17 / 40 as of 10/15/09

Tx: C4-08-001 (dosing changes per cohort – pls consult study) po (D1-21) q 28 days

Eligibility: malignancy or lymphoproliferative disorder known to over express CK2 which have failed standard therapies, life expectancy > 12 wks, Karnofsky PS  $\geq$  70%, prior brain mets OK as long tx and well controlled > 3 mo, major sx must be > 4 wks out, prior tx for current malignancy must be > 3 wks out,

Ineligibility: chronic diarrhea, any history of gastric or small bowel surgery

## Brain

### **N0776 Phase II Trial of Avastin in Combination with Sorafenib in Recurrent Glioblastoma Multiforme**

Study Activated: 9/12/08

Accrual: 35 / 53 as of 11/20/09

\*\*\*Pre-Registration Path Review required before patient can be registered to study.\*\*\*

Tx: Sorafenib + Avastin until progression (dosing and tx schedule variable – is dose limiting; please consult protocol)

Eligibility: GBM or gliosarcoma, evidence of progression following most recent anti-tumor tx, bidimensionally measurable disease,  $\geq$  12 weeks since prior RT, ECOG PS 0-2, fixed or < dose of steroids, > 4 wks from prior chemo (>6 wks from nitrosoureas)

Ineligibility: pts receiving enzyme-inducing antiepileptic drugs, prior intratumoral treatment unless new lesion identified, therapeutic anti-coagulation w/ Coumadin, MI/TIA/stroke w/in 6 months, any evidence of CNS hemorrhage on baseline scans

## Breast

### Neoadjuvant

### **N063D [ALLTO: Adjuvant Lapatinib and/or Trastuzumab Optimization Study] A Randomized, Multi-Centre, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 Positive Primary Breast Cancer**

Study Activated: 2/11/08

Accrual: 335 / 8000 as of 11/20/09

\*\*\*After completion of (neo) adjuvant chemo and/or surgery:

I: Taxol + Herceptin q wk x 12 → Herceptin q 3 wks x 40 weeks

II: Taxol q wk x 12 + Lapatinib 1500mg po qd x 1 year

III: Taxol + Herceptin q wk x 12 → Lapatinib 1500mg po qd x 34 weeks

IV: Taxol + Herceptin q wk x 12 + Lapatinib 1000mg po qd → Herceptin q 3 wk + Lapatinib 1000mg po qd x 40 wks

Eligibility: adenocarcinoma, ECOG PS 0-1, deep margin/pT4 OK as long as RT given, node +/-, ER/PR +/-, tumor  $\geq$  1.0cm, pts must have received 4 cycles of an approved anthracycline based (neo)/adjuvant regimen

Ineligibility: metastatic disease, prior breast ca, clinically T4, bilateral or multifocal disease, prior stem cell tx, supraclavicular nodal involvement, any hx of transmural infarction

**TEMPORARLY CLOSURE 10/21/09 DUE TO LAPATINIB RISKS ACTION LETTER  
PROTOCOL TO RE-OPEN 12/9/09**

**NSABP B-41 A Randomized Phase III Trial of Neoadjuvant Therapy for Patients with Palpable and Operable HER-2 Positive Breast Cancer Comparing the Combination of Trastuzumab Plus Lapatinib to Trastuzumab and to Lapatinib Administered with Weekly Paclitaxel Following AC Accompanied by Correlative Science Studies to Identify Predictors of Pathologic Complete Response**

Study Activated: 6/12/07

Accrual: 239 / 522 as of 11/20/09

I: AC q 21 days x 4 cycles → Taxol (D 1, 8, 15) q 28 days x 4 cycles + Herceptin weekly until Surgery → Surgery → Herceptin q 21 days until 1 year following the first preoperative dose of Herceptin

II: AC q 21 days x 4 cycles → Taxol (D 1, 8, 15) q 28 days x 4 cycles + Lapatinib qd until Surgery → Surgery → Herceptin q 21 days until 1 year following the first preoperative dose of Lapatinib

III: AC q 21 days x 4 cycles → Taxol (D 1, 8, 15) q 28 days x 4 cycles + Herceptin weekly + Lapatinib qd until Surgery → Surgery → Herceptin q 21 days until 1 year following the first preoperative dose of Herceptin

Eligibility: life expectancy ≥ 10 years, ECOG PS 0-1, tumor must be palpable and measure ≥ 2cm by physical exam, diagnosis must have been made by core needle biopsy, history of LCIS OK

Ineligibility: men, diagnosis via FNA only, excisional biopsy/lumpectomy/axillary staging performed prior to randomization, clinical T4 tumors, ipsilateral cN<sub>2b</sub> or cN<sub>3</sub> disease, evidence of metastatic disease, prior history of breast cancer or DCIS, neuropathy ≥ grade 2

**Adjuvant: Bisphosphonates**

**CTSU / S0307 Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer**

Study Activated: 11/15/05

Accrual: 5003 / 5400 as of 11/20/09

I: Zoledronic Acid IV q mo x 6 months → q 3 months x 2.5 years

II: Clodronate po qd x 3 years

~~III: Ibandronate po qd x 3 years~~

Eligibility: invasive adenocarcinoma, stages I/II/III, neoadjuvant tx OK but enrollment must be after surgery, pts may be enrolled prior to/simultaneously with/after beginning adjuvant tx, pts receiving hormonal/neoadjuvant tx should be registered < 84 days from surgery, pts receiving chemo should be enrolled <56 days after completing it, additional biological/RT tx is OK at any time before or after registration, Zubrod PS 0-2, pts currently being tx w/ bisphosphonates for bone density are OK as long as d/c prior to registration, pts must have a dental exam w/in 6 months prior to study, hx of GERD OK

Ineligibility: metastatic disease, pts who receive biological agents or RT only w/o chemo or hormonal tx, pts at low risk of recurrence that adjuvant tx is not recommended, pts w/ renal failure, PMH of esophageal stricture or motility disorder

**ARM C PERMANENTLY CLOSED TO ACCRUAL 9/1/09**

**Adjuvant: Receptor Positive**

**CTSU / IBCSG 24-02 A Phase III Trial of Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer**

Study Activated: 8/4/03

Accrual: 2657 / 3000 as of 11/18/09

I: Tamoxifen 20mg/day x 5 years

II: ovarian function suppression + Tamoxifen 20mg/day x 5 years

III: ovarian function suppression + Exemestane 25mg/day x 5 years

\*\*\*ovarian function suppression = triptorelin x 5 yrs OR surgical oophorectomy OR ovarian irradiation\*\*\*

Eligibility: histologically proven, completely resected, axillary node dissection or sentinel node required, pts who did not receive chemo must be randomized w/in 12 weeks of surgery, pts who received prior chemo must be registered w/in 8 months post chemo, pts w/ temporarily chemo-induced amenorrhea who regain premenopausal status w/in 8 months post chemo are eligible, no PS parameters

Ineligibility: postmenopausal women, metastatic disease, positive margins, locally advanced inoperable cancer, supraclavicular nodal involvement, inflammatory breast cancer, bilateral disease, prior hx of ipsilateral or contralateral invasive breast cancer, residual axillary disease, previous bilateral oophorectomy or ovarian RT, pts who are planning to have an oophorectomy w/in 5 yrs, previous tx w/ endocrine therapy > 6 months post diagnosis (including neoadjuvant & adjuvant), prior tx w/ tamoxifen or other SERM's w/in 1 year of diagnosis, prior tx w/ GnRH analogues for breast cancer, additional concurrent hormonal tx including for contraception

**CTSU / ANZ 0701 (Co-SOFT) Investigating Cognitive Function for Patients Participating in the SOFT Trial in Selected Centers**

Study Activated: 6/11/07

Accrual: 43 / 357 as of 11/2/09

Tx: Cognitive Functioning Test Battery at baseline, years 1, 5, 6

Eligibility: pts must be registered to SOFT parent study, pts must not have started SOFT protocol tx yet, must be able to speak English fluently

**NSABP B-42 A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer**

Study Activated: 7/12/06

Accrual: 3549 / 3840 as of 11/20/09

I: Placebo x 5 yrs

II: Letrozole 2.5mg x 5 yrs

Eligibility: postmenopausal, ECOG PS 0-1, stages I / II / IIIA, ER and/or PR +, lumpectomy or mastectomy w/ appropriate nodal staging, duration of previous AI therapy must be b/w 57-63 months, if pts started on Tamoxifen can only take for up to 3 years before switching to an AI, randomization w/in 6 months of last dose of adjuvant hormonal therapy, BMD and lipid panel required

Ineligibility: pts requiring ovarian suppression to be postmenopausal, Tamoxifen given for years 4 & 5 of adjuvant hormonal therapy, hx of non-traumatic osteoporotic fracture or wrist/hip/spine, contralateral breast ca including DCIS

***OPTIONAL LETROZOLE REGISTRATION PROGRAM PERM. CLOSED TO ACCRUAL 9/5/08***

**Adjuvant: Node Negative**

**N083E Phase II Safety Study of Docetaxel and Carboplatin in Combination with Trastuzumab and Lapatinib in Early Breast Cancer**

Study Activated: 3/6/09

Accrual: 30 / 33 as of 11/20/09

Tx: Taxotere 75mg/m<sup>2</sup> (D1) + Carbo AUC 6 (D1) + Herceptin 2mg/kg (D1, 8, 15) + Lapatinib 1000mg po (D1-21) q 21 days for 6 cycles → Herceptin 6mg/kg (D1) + Lapatinib 1000mg po (D1-21) q 21 days x 12 cycles

Eligibility: men or women, ECOG PS 0-1, adequately excised, pts w/ a + deep margin or pT4 OK as long as they get RT

Ineligibility: metastatic disease, inflammatory breast ca, hx of any prior breast ca, clinically staged T4 cancers, prior hx of receiving any chemo, + supraclavicular LN's

**N063D [ALLTO: Adjuvant Lapatinib and/or Trastuzumab Optimization Study] A Randomized, Multi-Centre, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 Positive Primary Breast Cancer**

Study Activated: 2/11/08

Accrual: 335 / 8000 as of 11/20/09

\*\*\*After completion of (neo) adjuvant chemo and/or surgery:

I: Taxol + Herceptin q wk x 12 → Herceptin q 3 wks x 40 weeks

II: Taxol q wk x 12 + Lapatinib 1500mg po qd x 1 year

III: Taxol + Herceptin q wk x 12 → Lapatinib 1500mg po qd x 34 weeks

IV: Taxol + Herceptin q wk x 12 + Lapatinib 1000mg po qd → Herceptin q 3 wk + Lapatinib 1000mg po qd x 40 wks

Eligibility: adenocarcinoma, ECOG PS 0-1, deep margin/pT4 OK as long as RT given, node +/-, ER/PR +/-, tumor ≥ 1.0cm, pts must have received 4 cycles of an approved anthracycline based (neo)/adjuvant regimen

Ineligibility: metastatic disease, prior breast ca, clinically T4, bilateral or multifocal disease, prior stem cell tx, supraclavicular nodal involvement, any hx of transmural infarction

***TEMPORARILY CLOSURE 10/21/09 DUE TO LAPATINIB RISKS ACTION LETTER  
PROTOCOL TO RE-OPEN 12/9/09***

**E5103 A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer**

Study Activated: 11/2/07

Accrual: 3493 / 4950 as of 11/20/09

I: AC + Placebo x 4 → T + Placebo x 4

II: AC + Avastin x 4 → T + Avastin x 4

III: AC + Avastin x 4 → T + Avastin x 4 → Avastin x 10 more cycles

Eligibility: men or women, registration b/w 28 & 84 days of surgery, ECOG PS 0-1, prior tx w/ Tamoxifen/Raloxifene for prevention OK, full dose anticoagulation OK

Ineligibility: HER2 + patients, inflammatory disease, fixed axillary nodes, prior chemo or hormonal therapy for breast cancer, prior tx w/ an anthracycline or taxane for any reason, MI w/in 12 months

**TEMPORARY SUSPENSION 9/24/09 – TOXICITY ISSUES WITH CONGESTIVE HEART FAILURE**

**Adjuvant: Node Positive**

**N083E Phase II Safety Study of Docetaxel and Carboplatin in Combination with Trastuzumab and Lapatinib in Early Breast Cancer**

Study Activated: 3/6/09

Accrual: 30 / 33 as of 11/20/09

Tx: Taxotere 75mg/m<sup>2</sup> (D1) + Carbo AUC 6 (D1) + Herceptin 2mg/kg (D1, 8, 15) + Lapatinib 1000mg po (D1-21) q 21 days for 6 cycles → Herceptin 6mg/kg (D1) + Lapatinib 1000mg po (D1-21) q 21 days x 12 cycles

Eligibility: men or women, ECOG PS 0-1, adequately excised, pts w/ a + deep margin or pT4 OK as long as they get RT

Ineligibility: metastatic disease, inflammatory breast ca, hx of any prior breast ca, clinically staged T4 cancers, prior hx of receiving any chemo, + supraclavicular LN's

**N063D [ALLTO: Adjuvant Lapatinib and/or Trastuzumab Optimization Study] A Randomized, Multi-Centre, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 Positive Primary Breast Cancer**

Study Activated: 2/11/08

Accrual: 335 / 8000 as of 11/20/09

\*\*\*After completion of (neo) adjuvant chemo and/or surgery:

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II: Taxol q wk x 12 + Lapatinib 1500mg po qd x 1 year

III: Taxol + Herceptin q wk x 12 → Lapatinib 1500mg po qd x 34 weeks

IV: Taxol + Herceptin q wk x 12 + Lapatinib 1000mg po qd → Herceptin q 3 wk + Lapatinib 1000mg po qd x 40 wks

Eligibility: adenocarcinoma, ECOG PS 0-1, deep margin/pT4 OK as long as RT given, node +/-, ER/PR +/-, tumor ≥ 1.0cm, pts must have received 4 cycles of an approved anthracycline based (neo)/adjuvant regimen

Ineligibility: metastatic disease, prior breast ca, clinically T4, bilateral or multifocal disease, prior stem cell tx, supraclavicular nodal involvement, any hx of transmural infarction

**TEMPORARILY CLOSURE 10/21/09 DUE TO LAPATINIB RISKS ACTION LETTER**

**PROTOCOL TO RE-OPEN 12/9/09**

**E5103 A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer**

Study Activated: 11/2/07

Accrual: 3493 / 4950 as of 11/20/09

I: AC + Placebo x 4 → T + Placebo x 4

II: AC + Avastin x 4 → T + Avastin x 4

III: AC + Avastin x 4 → T + Avastin x 4 → Avastin x 10 more cycles

Eligibility: men or women, registration b/w 28 & 84 days of surgery, ECOG PS 0-1, prior tx w/ Tamoxifen/Raloxifene for prevention OK, full dose anticoagulation OK

Ineligibility: HER2 + patients, inflammatory disease, fixed axillary nodes, prior chemo or hormonal therapy for breast cancer, prior tx w/ an anthracycline or taxane for any reason, MI w/in 12 months

**TEMPORARY SUSPENSION 9/24/09 – TOXICITY ISSUES WITH CONGESTIVE HEART FAILURE**

### Adjuvant: Radiation Therapy

#### **NSABP B-39 / RTOG 0413 A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) vs Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer**

Study Activated: 3/21/05

Accrual: 3608 / 4300 as of 11/20/09

I: WBI 45-50 Gy in 25 (1.8-2.0 Gy) fractions to whole breast, followed by optional boost to  $\geq 60$  Gy (to follow chemo if needed)

II: PBI 38.5 Gy in 3.85 Gy fractions using 3D conformal external beam radiation: RT given to index quadrant only, BID (with a fraction separation of at least 6 hours), for a total of 10 treatments given on 5 days over a period of 5 to 10 days (chemo to follow)

Eligibility: life expectancy  $\geq 10$  yrs, tumor size  $\leq 3$ cm, DCIS or invasive adenocarcinoma, lumpectomy required w/ clear margins, re-excision of surgical margins OK, gross disease must be unifocal, microscopic disease can be multi-focal as long as total size  $\leq 3$ cm, axillary staging not required w/ DCIS, invasive cancer: ALND ( $\geq 6$  nodes) or SLND (if neg no more nodes required, if pos 6 axillary nodes required),  $\leq 42$  days from surgery to randomization, lumpectomy cavity must be clearly delineated, target lumpectomy cavity/whole breast reference volume must be  $\leq 30\%$  based on post-op/pre-randomization CT scan, hx of LCIS OK, previous hormonal tx OK as long as treated  $\leq 28$  days

Ineligibility: men,  $> 3$  positive lymph nodes, axillary nodes w/ microscopic or macroscopic extracapsular extension,  $\geq 1$  + non-axillary sentinel node(s), multicentric disease (in more than one quadrant or separated by  $\geq 4$ cm's), Paget's disease, bilateral ca, hx of invasive breast ca or DCIS, regional nodal RT, previous RT/chemo/biologic tx for current diagnosis, breast implants, palpable or radiographically suspicious ipsilateral or contralateral axillary/supra/infraclavicular/internal mammary nodes unless biopsied

**ATTENTION: STUDY HAS CLOSED ACCRUAL TO THE FOLLOWING STRATA OF PTS 12/30/06:**

**A. Women  $\geq 50$  years w/ DCIS**

**B. Women w/ invasive ca who are  $\geq 50$  years AND node negative AND hormone receptor positive**

### Advanced / Metastatic

#### **CTSU / C40502 A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound Nab-Paclitaxel or Ixabepilone Combined With Bevacizumab as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer**

Study Activated: 10/13/08

Accrual: 188 / 900 as of 11/18/09

I: Taxol 90mg/m<sup>2</sup> (D1, 8, 15) + Avastin 10mg/kg (D1, 15) q 28 days until progression

II: Abraxane 150mg/m<sup>2</sup> (D1, 8, 15) + Avastin 10mg/kg (D1, 15) q 28 days until progression

III: Ixabepilone 16mg/m<sup>2</sup> (D1, 8, 15) + Avastin 10mg/kg (D1, 15) q 28 days until progression

Eligibility: stage IIIB not amenable to local therapy or stage IV, HER2+ pts OK as long as previous tx w/ herceptin or lapatinib, neo/adjuvant tx ok as long as  $> 12$  months ago, bisphosphonates ok, prior Avastin ok, prior RT ok as long as  $> 2$  wks ago, measurable disease, ECOG PS 0-1, life expectancy  $> 12$  wks

Ineligibility: prior chemo for stage IIIB/IV cancer, stroke/MI/TIA w/in 6 months, untreated CNS disease

#### **NSABP B-37 (IBCSG 27-02) A Randomized Clinical Trial of Adjuvant Chemotherapy for Radically Resected Loco-Regional Relapse of Breast Cancer: Chemotherapy vs Observation**

Study Activated: 1/14/05

Accrual: 157 / 265 as of 11/20/09

I: Observation (+/- Radiation Therapy)  $\rightarrow$  hormonal therapy/herceptin (if applicable)

II: Chemotherapy (+/- Radiation Therapy)  $\rightarrow$  hormonal therapy/herceptin (if applicable)

Eligibility: histologically verified 1<sup>st</sup> local and/or regional (ipsilateral axillary or internal mammary lymph node) recurrence of invasive breast cancer following primary treatment w/ mastectomy or breast conserving treatment, surgical margins can be clear or microscopically positive

Ineligibility: evidence of metastatic disease (including positive ipsilateral supraclavicular lymph nodes), evidence of macroscopically involved margins, bilateral malignancy (except in-situ), prior recurrence(s), skeletal pain of unknown cause

## Gastrointestinal

### Anal Canal

#### **E3205 Phase II Trial of Cetuximab Plus Cisplatin, 5-FU and Radiation in Immunocompetent Patients with Anal Carcinoma**

Study Activated: 1/12/07

Accrual: 30 / 62 as of 11/14/09

~~I: Induction Chemo (Cisplatin + 5-FU days 1-49) → Post-Induction Chemo/RT (C225 + Cisplatin + 5-FU + RT days 50+)~~

II: C225 weekly + Cisplatin 75mg/m<sup>2</sup> (D8, 36) + 5-FU 1000mg/m<sup>2</sup> CI x 4 days (D 8-11, 36-39) + RT starting D8 x 5 weeks

Eligibility: stage II (T3N0 only) or IIIA/IIIB, invasive anal margin squamous cell carcinoma, basoloid/transitional cell/cloacogenic histology OK, ECOG PS 0-2

Ineligibility: well differentiated stage I anal margin cancer, prior RT/chemo for anal cancer, hx of any pelvic RT, prior potentially curative surgery, MI w/in 6 months, rheumatic disorder, IBS, HIV+

***INDUCTION TREATMENT NO LONGER A PART OF THE STUDY AS OF 8/18/09***

### Carcinoid

#### **CTSU / S0518 Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha versus Depot Octreotide Plus Bevacizumab in Advanced, Poor Prognosis Carcinoid Patients**

Study Activated: 12/1/07

Accrual: 173 / 283 as of 11/13/09

I: Octreotide + Avastin q 21 days until progression

II: Octreotide q 21 days + Interferon 3 times a week until progression

Eligibility: unresectable or locally advanced, low/intermediate grade neuroendocrine carcinoma, measurable disease, 1 prior chemo regimen/hepatic artery embolization/RT OK but must be > 28 day out, prior Octreotide OK but must be > 21 days ago, Zubrod PS 0-2

Ineligibility: medullary or islet cell carcinoma, prior tx w/ interferon/avastin/VEGF inhibitors, CNS mets

### Colon / Rectum

#### Adjuvant

#### **E5202 A Randomized Phase III Study Comparing mFOLFOX6 +/- Avastin in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers**

Study Activated: 8/4/05

Accrual: 1968 / 3610 as of 11/14/09

\*\*\*Tumor block risk assessment w/in 50 days of surgery: High-Risk vs Low-Risk\*\*\*

High-Risk: mFOLFOX6 q 14 days x 12 cycles vs mFOLFOX6 + Bevacizumab q 14 days x 12 cycles

Low-Risk: Observation

Eligibility: tumor > 12cm from anal verge, paraffin block submission required, T<sub>3-4</sub>N<sub>0</sub>M<sub>0</sub>, pts must have ≥ 8 lymph nodes sampled and evaluated, ECOG PS 0-2, adjuvant tx must begin > 28 and < 60 days from surgery

Ineligibility: isolated/distant/non-contiguous mets, bowel obstruction or perforation, prior tx for this cancer, prior significant bleeding not related to tumor, active gastroduodenal ulcers, ≥ grade 2 peripheral neuropathy, any hx of TIA or CVA, MI w/in 12 months

## **CTSU / N0147 A Randomized Phase III Trial of Oxaliplatin + 5FU / Leucovorin With or Without Cetuximab After Curative Resection for Patients With Stage III Colon Cancer**

Study Activated: 2/10/04

Accrual: 3382 / 3768 as of 11/20/09

I: FOLFOX q 2 wks x 12 cycles

II: FOLFOX q 2 wks x 12 cycles + C225 (D1, 8) x 12 cycles

Eligibility: adenocarcinoma, tumor must be  $\geq 12$  cm from anal verge, complete resection of tumor required, pts w/ tumor-related obstruction or colonic perforation are eligible,  $\geq 1$  + lymph node required, registration  $\leq 56$  days post surgery, pts w/  $> 1$  synchronous primary colon cancer OK, ECOG PS 0-2

Ineligibility: residual lymph node disease, distant mets, prior chemo/RT/anti-EGFR agents for colon cancer, symptomatic pulmonary fibrosis or interstitial pneumonitis, infection, uncontrolled HTN, unstable angina, symptomatic CHF, MI w/in 6 months,  $\geq$  grade II neuropathy at time of entry, history of GI bleed not appropriately addressed by MD

### **Advanced / Metastatic**

## **N054C Phase II Study of Sorafenib/Bevacizumab as Salvage Therapy in Patients with Metastatic Colorectal Cancer**

Study Activated: 5/13/09

Accrual: 83 / 77 as of 11/20/09

Tx: Avastin 5mg/kg (D1) + Sorafenib 200mg po bid (D1-5 and 8-12) q 2 wks until progression

Eligibility: progressive disease during current tx or w/in 6 mo's of recent chemo, prior chemo must have included 5-FU or oxaliplatin or irinotecan, KRAS testing must have been done previously and wild type pts must have rec'd anti-EGFR tx, prior RT ok, measurable disease, ECOG PS 0-1, life expectancy  $> 6$  mo

Ineligibility: prior sorafenib, brain mets, MI/angina/CVA/PE w/in 6 mo, malabsorption problems, previously d/c Avastin d/t SE's

**TEMPORARY SUSPENSION 10/20/09 – ACCRUAL GOAL MET**

## **CTSU / C80405 A Phase III Trial of FOLFIRI or FOLFOX with Bevacizumab, or Cetuximab, or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Locally Advanced or Metastatic Adenocarcinoma of the Colon or Rectum**

Study Activated: 9/15/05

Accrual: 1627 / 2843 as of 11/18/09

I: FOLFOX or FOLFIRI + Avastin (5mg/kg) q 2 wks until progression

II: FOLFOX or FOLFIRI q 2 wks + Cetuximab weekly until progression

~~III: FOLFOX or FOLFIRI + Avastin (5mg/kg) q 2 wks + Cetuximab weekly until progression~~

Eligibility: life expectancy  $\geq 12$  wks, prior adjuvant chemo OK as long as  $> 12$  months ago, prior RT OK as long as  $< 25\%$  of bone marrow and occurred  $\geq 4$  weeks ago, major surgery must be completed  $\geq 4$  weeks ago/minor surgery  $\geq 2$  weeks ago, pathologic specimen must be available for tissue banking, pts w/ colostomy or ileostomy may be entered at MD's discretion, pts on full dose anti-coagulation OK as long as stable INR, pts receiving anti-platelet agents or aspirin or treatment for a-fib OK, ECOG PS 0-1

Ineligibility: any prior treatment for advanced or metastatic disease, pts w/ evidenced of Gilbert's syndrome who are to receive FOLFIRI (FOLFOX OK), baseline peripheral neuropathy  $\geq$  grade 2 for pts who are to receive FOLFOX, known CNS mets, interstitial pneumonia or extensive and symptomatic interstitial fibrosis of the lung, pleural effusion or ascites that causes  $\geq$  grade 2 dyspnea, predisposing colonic or small bowel disorders which are uncontrolled ( $> 3$  watery stools/day in pts w/out colostomy or ileostomy), significant history of bleeding events w/in last 6 months unless source of bleeding resected, GI perforation w/in last 12 months, arterial thrombotic events w/in 6 months of registration

**ARM C PERMANENTLY CLOSED 9/15/09 – NO OVERALL SURVIVAL BENEFIT WAS FOUND**

## Pancreas

### **N064A A Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with Locally Advanced Pancreatic Cancer**

Study Activated: 6/19/09

Accrual: 12 / 50 as of 11/20/09

Tx: RT 5 days/wk for 5.5 wks + Panitumumab (D1, 15, 29) + 5-FU CI throughout RT → 4-6 wks afterwards Gemzar (D1, 8, 15) + Panitumumab (D1, 15) q 28 days x 3 cycles → maintenance Panitumumab (D1, 15) q 28 days x 6 cycles → observation

Eligibility: histo/cytologically confirmed unresectable adenocarcinoma (includes subtotal resection or gross residual disease), measurable disease not required, ECOG PS 0-1, disease that is encompassable w/in standard RT fields, laparotomy > 21 days ago

Ineligibility: evidence of mets outside RT field, distant mets, microscopic residual disease only, current nausea or vomiting > grade 1, history of interstitial lung disease, cystadenocarcinomas or neuroendocrine tumors, CNS mets, enteral hyperalimentation

## Genitourinary

### Urinary Tract

### **CTSU / C90601 A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma**

Study Activated: 7/15/09

Accrual: 1 / 500 as of 11/18/09

Tx: Gemzar 1000mg/m<sup>2</sup> (D1, 8) + Cisplatin 70mg/m<sup>2</sup> (D1) + Avastin/Placebo 15mg/kg (D1) q 21 days x 6 cycles → Avastin/Placebo until progression

Eligibility: metastatic or unresectable carcinoma of the urinary tract (T4b, N2-3, M1), prior chemo for radiosensitizing OK, prior neo/adjuvant chemo OK as long as > 1 yr ago, prior radiation/intravesical treatment ok as long as > 28 days ago, ECOG PS 0-1

Ineligibility: pts who are candidates for potentially curative surgery or RT, prior chemo for metastatic disease, prior Avastin or other angiogenesis inhibitors, known brain mets, peritoneal carcinomatosis, peripheral neuropathy ≥ grade 2

### Prostate

#### Ancillary Studies

### **S0000B Prevention of Cataract and Age-Related Macular Degeneration with Vitamin E and Selenium SELECT Eye Endpoints (SEE), Phase III Ancillary to S0000 (SELECT)**

Study Activated: 7/1/04

Accrual: 2426 as of 11/13/09

Ancillary to SELECT, medical records collection

#### Hormone Refractory

### **CTSU / S0421 Phase III Study of Docetaxel and Atrasetan versus Docetaxel and Placebo for Patients With Advanced Hormone Refractory Prostate Cancer**

Study Activated: 8/21/06

Accrual: 827 / 930 as of 11/13/09

Tx: Docetaxel 75mg/m<sup>2</sup> q 21 days + Prednisone 10mg qd + Atrasetan/Placebo 10mg qd x 36 weeks → Atrasetan/Placebo x 3mo's

Eligibility: measurable/non-measurable, pts must have evidence of bone mets, prior RT or surgery OK but must be > 21 days out, 1 prior chemo regimen OK but must be > 28 days out, Zubrod PS 0-3

Ineligibility: starting bisphosphonates after initiating study therapy, peripheral neuropathy  $\geq$  grade 2, hx of or current brain mets, pts w/ 3<sup>rd</sup> space fluid accumulation

## Metastatic

### **E3805 CHARTED: ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease Prostate Cancer**

Study Activated: 7/28/06

Accrual: 223 / 600 as of 11/14/09

I: Androgen Deprivation (until progression) + Docetaxel 75mg/m<sup>2</sup> q 21 days x 6 cycles

II: Androgen Deprivation alone until progression

Eligibility: pts can begin hormonal therapy as long as < 120 days ago, metastatic disease, measurable or non-measurable, ECOG PS 0-2, pts can have rec'd prior neo/adjuvant tx – pls see protocol for prior tx guidelines, prior palliative RT ok

Ineligibility: PSA rising > 50% from lowest point b/w starting androgen ablation and randomization, neuropathy  $\geq$  grade 2

## Renal

### **E2804 A Randomized Phase II Study of VEGF, RAF kinase, and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma**

Study Activated: 9/14/07

Accrual: 226 / 360 as of 11/14/09

I: Avastin 10mg/kg q 2 wks until progression

II: Temsirolimus 25mg weekly + Avastin 10mg/kg q 2 wks until progression

III: Avastin 5mg/kg q 2 wks + Sorafenib 200mg po bid (D1-5, 8-12, 15-19, 22-26) until progression

IV: Sorafenib 200mg po bid + Temsirolimus 25mg weekly until progression

Eligibility: clear cell w/ < 25% any other histology, measurable metastatic disease, nephrectomy required (please see protocol regarding exceptions), one prior regimen w/ a vaccine or cytokine OK, Thalidomide/Interferon-alpha OK for adjuvant or metastatic disease, prior RT OK as long as > 2 wks out, ECOG PS 0-1, life expectancy > 12 wks

Ineligibility: any prior anti-angiogenic therapy except thalidomide or interferon alpha, CNS disease, hx of bleeding diathesis

## Gynecological

### Cervical

(none)

### Endometrial

(none)

### Ovarian

(none)

## Head & Neck

### **E1305 A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer**

Study Activated: 8/8/08

Accrual: 33 / 400 as of 11/14/09

\*MD to decide if patient going to receive Cisplatin 75 mg/m<sup>2</sup> + Taxotere 75mg/m<sup>2</sup> OR Cisplatin 100mg/m<sup>2</sup> + 5-FU 1000mg/m<sup>2</sup>/day CI x 4 days. Once decided, then patient randomized to:

I. Cisplatin doublet q 21 days until progression (or after 6 cycles if pt has reached max response)

II. Cisplatin doublet + Avastin 15mg/kg q 21 days until progression (or after 6 cycles if pt has reached max response). Avastin can continue after chemo until progression.

Eligibility: SCCHN from any primary, pts who refuse radical resection for recurrent disease are OK, one prior regimen of induction/concomitant chemoRT/adjuvant chemo OK for curative intent but must be > 6 months ago, ECOG PS 0-1, measurable disease

Ineligibility: nasopharyngeal carcinoma histologic types WHO 2 or 3, squamous cell carcinoma that originated from the skin, prior chemo/biological therapy for recurrent/met disease, known brain mets, tumors that have invaded major vessels ie: carotid, hx of coagulopathy or hemorrhagic disorders, concurrent tx for DVT/PE, aspirin usage > 325mg/day, hypercalcemia related to H & N cancer, angina or MI w/ in 6 months, symptomatic CHF, presence of aneurysm > 6cm

## Leukemia

### AML / CMMoL

#### **E1905 A Randomized Phase II Trial of Azacitidine +/- the Histone Deacetylase Inhibitor Entinostat for the Treatment of Myelodysplastic Syndrome, Chronic Myelomonocytic Leukemia (dysplastic type) and Acute Myeloid Leukemia with Multilineage Dysplasia**

Study Activated: 8/18/06

Accrual: 153 / 196 as of 11/14/09

I: Azacitidine 50mg/m<sup>2</sup> subcutaneously once daily, days 1-10 q 28 days x 6 cycles → if PR/CR then continue w/ 18 more cycles of tx  
II: Azacitidine 50mg/m<sup>2</sup> subcutaneously once daily, days 1-10 + MS-275 4 mg/m<sup>2</sup> orally days 3 & 10 q 28 days x 6 cycles → if PR/CR then continue w/ 18 more cycles of tx

Eligibility: all diagnoses must be made by BMBx w/in 2 weeks prior to registration, ECOG PS 0-2, must be > 3 wks out from previous growth factors, life expectancy > 6 months

Ineligibility: any prior tx for these cancers including induction chemo & stem cell transplant, evidence of CNS or pulmonary leukostasis, disseminated intravascular coagulation, CNS leukemia, therapy-induced MDS or AML, advanced hepatic tumors

**\*\*\*STUDY OPEN TO TREATMENT RELATED MDS/AML/CML PATIENTS ONLY\*\*\***

## Lung

### Ancillary Studies

#### **CTSU / S9925 Lung Cancer Specimen Repository Protocol, Ancillary**

Study Activated: 9/1/00

### Non-Small Cell: Advanced / Metastatic

#### **N0821 A Phase II First-Line Study of a Combination of Pemetrexed, Carboplatin and Bevacizumab in Advanced Nonsquamous NSCLC Evaluating Efficacy and Tolerability in Elderly Patients (Age ≥ 70 yrs) with Good Performance Status (PS < 2)**

Study Activated: 12/12/08

Accrual: 24 / 60 as of 11/20/09

Tx: Pemetrexed 500mg/m<sup>2</sup> + Carbo AUC 6 + Avastin 15mg/kg D1 q 21 days x 6 cycles → if SD/PR/CR then Pemetrexed 500mg/m<sup>2</sup> + Avastin 15mg/kg D1 q 21 days until progression

Eligibility: stage IIIB/IV, measurable disease, prior RT OK as long as > 2 wks out and < 25% of BM radiated, life expectancy > 12 wks, pts must be willing to enroll on N0392 (Assessment of Patient Satisfaction w/ Participation in Phase II/III NCCTG Trials), neoadjuvant or adjuvant tx > 12 months out for lung ca OK

Ineligibility: inability to interrupt NSAIDs, symptomatic/uncontrolled CNS disease, prior chemo for advanced lung ca, symptomatic pleural effusion, hx of diverticulitis w/in 12 months, major surgery < 8 wks prior to study, hemoptysis > ½ tsp, MI/stroke < 6 months

**SEE N0392 IN CANCER CONTROL/MISC STUDIES**

#### **CTSU / C30607 Randomized, Phase III, Double-Blind Placebo-Controlled Trial of Sunitinib as Maintenance Therapy in Non-Progressing Patients Following an Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB/IV Non-Small Cell Lung Cancer**

Study Activated: 6/15/08

Accrual: 55 / 156 as of 11/18/09

Tx: Sunitinib or Placebo 37.5mg po qd until progression

Eligibility: Avastin OK but cannot give after 4 cycles of chemo, CR/PR/Stable disease after 1<sup>st</sup> line chemo, pts must be registered > 3 wks and < 5 wks from completing chemo, palliative RT OK as long as completed 1 wk prior to start of study tx, measurable or non-measurable disease, ECOG PS 0-1

Ineligibility: patients who are candidates for chemoRT, evidence of CNS disease, cavitory lesions, prior chemo for resected stage I-III lung ca, any combined modality tx given for NSCLC, concurrent therapeutic anticoagulation, hx of DVT/PE, severe cardiac issues

### **E1505 A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (≥ 4cm) - IIIA Non-Small Cell Lung Cancer**

Study Activated: 6/1/07

Accrual: 525 / 1500 as of 11/14/09

I: 1 of 3 chemo regimens\* q 3 wks x 4 cycles

II: 1 of 3 chemo regimens\* + bevacizumab 15mg/kg q 3 wks x 4 cycles → bevacizumab q 3 wks x 1 year

\*chemo regimens allowed: 1) Vinorelbine/Cisplatin 2) Docetaxel/Cisplatin 3) Gemzar/Cisplatin

Eligibility: complete resection (lobectomy, sleeve resection, bi-lobectomy, pneumonectomy) w/ mediastinal LND, T<sub>2-3</sub>N<sub>0</sub>, T<sub>1-3</sub>N<sub>1-2</sub>, pts must be > 6 but <12 wks from surgery, ECOG PS 0-1, daily aspirin or NSAIDs OK, stable dose of anticoagulants OK

Ineligibility: resections via segmentectomy or wedge, prior chemo at any time, hormonal/biologic/RT for any cancer < 5 years ago, MI w/in 12 months, any history of CVA or TIA, post-op hemoptysis (1/2 teaspoon or more)

## **Lymphoma**

### **CTSU / S0816 A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma Using Early Interim PDG-PET Imaging**

Study Activated: 7/1/09

Accrual: 4 / 200 as of 11/13/09

Tx: ABVD Regimen: (pls see protocol for dosing guidelines) q 28 days x 2 cycles → PET scan done and sent to DICOM → results given via 5 pt scoring system → If PET negative, then patients to receive 4 more cycles of starting ABVD regimen, If PET positive, then patients to switch to BEACOPP regimen (please see protocol for dosing guidelines) q 21 days x 6 cycles

Eligibility: previously untreated, pts must be ≤ 60 yrs old, bidimensionally measurable disease, BMBx w/in 42 days, CT scan w/ contrast AND PET required (PVHS PET scanner cannot be used for the CT portion of this study – must be obtained separately d/t our PET scanner does not use oral/IV contrast for the CT portion), Zubrod PS 0-2, HIV status must be known

Ineligibility: nodular lymphocyte predominant, pts > 60 yrs old, prior chemo/RT/antibody tx for lymphoma, hep B or C + pts

## **Mesothelioma**

(none)

## **Multiple Myeloma**

### **E1A06 An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) Versus Melphalan, Prednisone and Lenalidomide (MPR) in Newly Diagnosed Multiple Myeloma Patients Who Are Not Candidates for High-Dose Therapy**

Study Activated: 2/29/08

Accrual: 166 / 560 as of 11/13/09

I: Melphalan 9mg/m<sup>2</sup> (D1-4) + Prednisone 100mg (D1-4) + Thalidomide 100mg qd + Aspirin 325mg qd q 28 days x 12 cycles → Thalidomide 100mg qd + Aspirin 325mg qd until progression

II: Melphalan 5mg/m<sup>2</sup> (D1-4) + Prednisone 100mg (D1-4) + Lenalidomide 10mg (D1-21) + Aspirin 325mg qd q 28 days x 12 cycles → Lenalidomide 10mg (D1-21) + Aspirin 325mg qd until progression

Eligibility: symptomatic w/ evidence of end organ damage, plasmacytosis w/ ≥ 10% plasma cells, sheets of plasma cells or biopsy proven plasmacytoma, pts must be > 65 y.o. and have declined alternative treatment OR b/w 18 and 65 and are not a

candidate/declined autologous stem cell transplant, ECOG PS 0-2, bisphosphonates OK, prior tx w/ prednisone or decadron OK as long as given < 4 wks total alone OR in combo w/ Thalidomide or Lenalidomide for < 2 wks,  
Ineligibility: smoldering myeloma, uncontrolled HTN/angina, hx of Stevens Johnson syndrome, peripheral neuropathy ≥ grade 2

## Myelodysplastic Syndrome & Myeloid Metaplasia

### **E1905 A Randomized Phase II Trial of Azacitidine +/- the Histone Deacetylase Inhibitor Entinostat for the Treatment of Myelodysplastic Syndrome, Chronic Myelomonocytic Leukemia (dysplastic type) and Acute Myeloid Leukemia with Multilineage Dysplasia**

Study Activated: 8/18/06

Accrual: 153 / 196 as of 11/13/09

I: Azacitidine 50mg/m<sup>2</sup> subcutaneously once daily, days 1-10 q 28 days x 6 cycles → if PR/CR then continue w/ 18 more cycles of tx

II: Azacitidine 50mg/m<sup>2</sup> subcutaneously once daily, days 1-10 + MS-275 4 mg/m<sup>2</sup> orally days 3 & 10 q 28 days x 6 cycles → if PR/CR then continue w/ 18 more cycles of tx

Eligibility: all diagnoses must be made by BMBx w/in 2 weeks prior to registration, ECOG PS 0-2, must be > 3 wks out from previous growth factors, life expectancy > 6 months

Ineligibility: any prior tx for these cancers including induction chemo & stem cell transplant, evidence of CNS or pulmonary leukostasis, disseminated intravascular coagulation, CNS leukemia, therapy-induced MDS or AML, advanced hepatic tumors

**\*\*\*STUDY OPEN TO TREATMENT RELATED MDS/AML/CML PATIENTS ONLY\*\*\***

## Sarcoma

(none)

## Skin

### Melanoma

### **N0775 A Randomized Phase III Trial of Temozolomide and Avastin or ABI-007/Carboplatin and Avastin in Patients with Unresectable Stage IV Malignant Melanoma**

Study Activated: 8/15/08

Accrual: 81 / 86 as of 11/20/09

I: ~~Temodar 200mg/m<sup>2</sup> po (D1-5) + Avastin 10mg/kg (D1, 15) q 28 days until progression~~

II: Avastin 10mg/kg (D1, 15) + ABI-007 100mg/m<sup>2</sup> (D1, 8, 15) + Carbo AUC 6 D1 until progression

Eligibility: prior adjuvant chemo/immunotherapy OK, measurable disease, life expectancy > 4 months, ECOG PS 0-2

Ineligibility: brain mets, investigations agents given < 4 wks prior to registration, prior chemo given for metastatic melanoma, prior exposure to any taxane, < 4 wks since last RT

**ARM A PERMANENTLY CLOSED 8/21/09 – ACCRUAL GOAL MET**

## Cancer Control / Miscellaneous Studies

### **N0392 Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials**

Study Activated: 6/7/06

Accrual: 226 / 3870 as of 11/20/09

\*\*\*Patient registered to an NCCTG treatment trial which has been designated as a parent trial to N0392, then:

Tx: “Control Preferences Scale” at baseline, then “Was It Worth It” Questionnaires at end of the 1<sup>st</sup> cycle and end of active treatment

Eligibility: pt needs to be able to complete booklets w/ aide of interpreter/family member/medical professional, etc

Ineligibility: cognitive impairment

**CTSU / S0702 A Prospective Observational Multicenter Cohort Study To Assess The Incidence Of Osteonecrosis Of The Jaw (ONJ) In Cancer Patients With Bone Metastases Starting Zoledronic Acid Treatment**

Study Activated: 12/15/08

Accrual: 181 as of 11/13/09

Tx: Zoledronic acid IV

Patients will undergo dental evaluation every 6 months. If ONJ develops, dental assessments will be performed every 3 months. Patients are followed for a total of 36 months.

Eligibility: bone mets from multiple myeloma/solid tumor/other malignancy where I.V. bisphosphonates indicated, Zubrod PS 0-3

Ineligibility: History of ONJ, hx of RT to jaw, > 90 days out since last bisphosphonate dose

Prestudy Requirements: ≤ 28 days of registration: History and physical exam

≤ 6 months before registration: Dental exam

≤ 12 months before registration: Dental imaging

**N07C2 The Use of Wisconsin Ginseng (panax quinquefolius) to Improve Cancer Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study**

Study Activated: 10/10/08

Accrual: 183 / 434 as of 11/20/09

\*\*\*Pts to take a linear analogue scale fatigue questionnaire. If pt has an average score  $\geq 4$  then eligible for study.\*\*\*

Tx: Wisconsin Ginseng vs Placebo 2000mg/day x 8 weeks

Eligibility: fatigue  $\geq 1$  month prior to study, ECOG PS 0-2, pts undergoing curative intent tx (including anti-hormonal) or pts who have completed tx and were diagnosed < 2 years ago, pt must have completed at least one cycle of tx before OK to enroll, pain and insomnia must be controlled, prior use of ginseng in teas or drinks OK as long as pt d/c prior to study, must be > 4 wks out from major surgery

Ineligibility: brain or CNS lymphoma, prior use of ginseng for fatigue, concomitant use of other non/pharmacologic agents to treat fatigue, chronic steroid use, diabetes, severe depression/OCD/mania, pain requiring opioid's, full dose anti-coagulation, MAO inhibitors, uncontrolled thyroid disorders, pts being treated on single agent blinded placebo controlled trials

**Closed Studies with Current or F/U Patients:****Breast**

E5194	97-278	10/22/02	2
E2197	99-368	1/21/00	2
E1199	00-400	1/8/02	2
E2104	05-765	11/6/06	1
E2Z04	07-854	12/23/08	1
NCCTG / C9741	98-295	3/31/99	2
NCCTG 9831	00-446	4/25/05	6
NSABP B-30	99-369	3/31/04	8
NSABP B-35	03-601	6/15/06	4
NSABP B-36	04-672	7/25/08	1
NSABP B-38	04-685	5/3/07	2
NSABP P-2	99-361	5/31/04	6
NCIC MA.27	03-617	7/31/08	24
NCIC MA.27B	06-776	5/30/08	4
NCIC MA.27D	06-772	7/31/08	2

**Colon**

NCCTG / C89803	99-386	5/15/01	2
NCCTG / S9415	98-348	12/15/99	1
NSABP C-07	00-423	11/15/02	2
NSABP C-08	04-687	10/6/06	2

**Endometrial**

GOG 0184	02-557	9/13/04	1
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**Lymphoma**

E2496	02-555	6/15/06	1
N0489	06-801	8/9/07	1
E2404	07-839	8/27/09	1
E4402	07-831	9/12/08	1
E1405	08-926	10/24/08	1

**Melanoma**

N0675	08-894	9/19/08	1
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**Ovarian**

GOG 0182	01-518	9/1/04	2
GOG 0218	06-778	8/10/09	6

**Prostate**

S0000	01-510	6/24/04	24
S0000A	02-574	9/30/09	17
C90401	05-738	12/21/07	1

**Sarcoma (GIST)**

ACOSOG Z9000	02-577	9/30/03	1
ACOSOG Z9001	02-578	4/18/07	1