ACTIVE CANCER CLINICAL TRIALS
March 2011

If you would like to speak with a research nurse please call one of the following:

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Changes made since previous listing:

Additions:

- **ECOG E1608** (Melanoma) - Open for accrual (page 4)
- **CTSU CALGB-50303** (Lymphoma) - Open for accrual (page 4)

Changes:

- **ECOG E2905** (MDS) - Reopened (page 4)
  
  *Per ECOG:* “ECOG has received notification from the NCI’s Pharmaceutical Management Branch that the erythropoetin alfa (Procrit) drug issues that required suspension of accrual have been resolved. Accrual of new patients to E2905 may now resume.”

- **ECOG E3508** (NSCLC) - Suspended (page 5)
  
  *Per ECOG:* “The study has accrued the patients necessary for the planned safety analysis. A notice will be sent … when the analysis is complete and new patient enrollment can resume.”

Closures:

- **ECOG 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*
  
  *Per ECOG:* “E5103 is approaching its accrual goal and will close to Step 1 accrual on February 28, 2011 … Patients randomized to Arm C who meet the protocol requirements for treatment completion may continue to register to Step 2.”

- **RTOG-0517**
  
  *Randomized Phase III Trial To Evaluate Radiopharmaceuticals And Zoledronic Acid In The Palliation Of Osteoblastic Metastases From Lung, Breast, And Prostate Cancer*
  
  *Per RTOG:* “will close to patient accrual … as the study has not met design requirements for the number of skeletal related events needed for the protocol-specified statistical analysis. A modified analysis plan is being developed based on the current patient enrollment.”

- **CTSU S0424** - Deleted
  
  *Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men*
  
  *Per SWOG:* The … study has reached its accrual goal”
**BRAIN**

Newly dx glioblastoma (WHO Grade IV) .................................................................................................................................. CTSU RTOG-0825

Initial 3 wks chemoradiation: RT (30Gy in 2Gy fx) + daily temozolomide (qd x 21d)

*then final 3 weeks of chemoradiation:*

RT (30Gy in 2Gy fx) + daily temozolomide (qd x 21d) + placebo q 2 wks

*then 4 wks after chemoradiation: temozolomide d1-5 of 28-d cycle + placebo q 2 wks; 12 cycle maximum*

vs

RT (30Gy in 2Gy fx) + daily temozolomide (qd x 21d) + bevacizumab q 2 wks

*then 4 wks after chemoradiation: temozolomide d 1-5 of 28-d cycle + bevacizumab q 2 wks; 12 cycle maximum*

**BREAST CANCER**

Locally recurrent or metastatic, first-line ................................................................................................................. CALGB-40502

Paclitaxel + Bevacizumab vs Nab-paclitaxel + Bevacizumab vsIxabepilone + Bevacizumab

Node positive or node negative > 1cm.................................................................................................................... CTSU N063D

Physician choice: Paclitaxel or Docetaxel or Docetaxel + Carboplatin with randomization to: ALTTO TRIAL

Trastuzumab alone for 1 yr

vs

Lapatinib alone for 1 yr

vs

Trastuzumab for 12 wks *then 6-wk break then* lapatinib for 34 wks

vs

Trastuzumab + lapatinib for 1 yr

Node positive or node negative > 2cm or high risk per investigator discretion (pre or post menopausal)................ CTSU S0221

\[84 \text{ days from mastectomy, axillary dissection or sentinel node detection} \]

Adriamycin/Cytoxan + Pegfilgrastim (q 2 wks x 4) *then* Taxol + Pegfilgrastim (q 2 wks x 6)

\((60 \text{mg/m}^2) \quad (600 \text{mg/m}^2)
\]

vs

Adriamycin/Cytoxan + Pegfilgrastim (q 2 wks x 4) *then* Taxol (q wk x 12)

\((60 \text{mg/m}^2) \quad (600 \text{mg/m}^2)
\]

HER2-Positive invasive breast cancer diagnosed by core needle biopsy, palpable mass \(\geq 2.0 \text{ cm} \) ........................................... NSABP B-41

IRB review pending -- Can be expedited upon request.

Paclitaxel + Trastuzumab

\[AC \quad \text{then} \quad \text{then} \quad \text{then} \quad \text{then} \]

Paclitaxel + Lapatinib

vs

Paclitaxel + Trastuzumab + Lapatinib

**GASTROINTESTINAL MALIGNANCIES - ESOPHAGEAL**

Esophageal cancer treated without surgery; \(\geq 18 \text{ and } < 75 \text{ yrs of age} \) ................................................. CTSU RTOG-0436

RT + Paclitaxel + Cisplatin + Cetuximab vs RT + Paclitaxel + Cisplatin

Second-line treatment for metastatic esophageal or GE junction ........................................................................ ECOG E2208

Paclitaxel vs Paclitaxel + Cixutumumab

**GASTROINTESTINAL MALIGNANCIES – COLON**

Resected stage I or II colon cancer .................................................................................................................... NSABP P-5

Rosuvastatin 10mg once daily x 5 years vs Placebo taken once daily x 5 years

Advanced, K-ras wild-type colorectal ca after progression on bevacizumab-containing chemo - Phase II........... ECOG E7208

Must have had prior first-line with oxaliplatin-based 5-FU chemo + bevacizumab for metastatic colorectal cancer

IRB review pending -- Can be expedited upon request.
GASTROINTESTINAL MALIGNANCIES – COLON OR RECTUM

Metastatic colon or rectum, KRAS normal (wild type) only

Bevacizumab then FOLFOX or FOLFIRI (investigator’s choice) vs Cetuximab then FOLFOX or FOLFIRI (investigator’s choice)

GENITOURINARY – RENAL

Advanced renal cell carcinoma progressing after tx with tyrosine kinase inhibitors

Everolimus + Placebo vs Everolimus + Bevacizumab

GENITOURINARY – BLADDER

Muscle-invasive bladder cancer, non-cystectomy candidates, Phase I/II

Her2/neu overexpression:

RT + Paclitaxel + Trastuzumab

No her2/neu overexpression:

RT + Paclitaxel

GENITOURINARY – PROSTATE

Prostate cancer metastatic to bone (no prior bisphosphonate or radiopharmaceuticals)

IRB review pending -- Can be expedited upon request.

Prevention of Erectile Dysfunction - stage T1b-T2b, M0 - Suspended due to problems with drug distribution

IRB review pending -- Can be expedited upon request.

Tadalafil vs Placebo (start within 7 days after start of RT)

GYN

Previously untreated, epithelial ovarian, fallopian tube, primary peritoneal

Stage II, III, or IV with either optimal (≤ 1 cm residual disease) or suboptimal residual disease

Cycles 1 - 6:

Paclitaxel IV days 1,8,15 + Carboplatin AUC 6 IV day 1 + Bevacizumab day 1 beginning cycle 2 vs Paclitaxel IV days 1,8,15 + Carboplatin AUC 6 IP day 1 + Bevacizumab day 1 beginning cycle 2 vs Paclitaxel 135mg/m² IV day 1 + Cisplatin 75mg/m² IP day 2 + Paclitaxel 60mg/m² IP day 8 + Bevacizumab day 1 beg cyc 2

Cycles 7 - 22 for all arms:

Bevacizumab day 1

HEAD AND NECK

Locally-advanced resected head and neck cancer -- Gross total resection of tumor; no prior chemo

RTOG 0920

T1N0,M0, T2N0,M0, T3, Microscopic T4a

RT (2 Gy/day, in 30 fractions for total of 60 Gy) vs Cetuximab then RT (as above) + Cetuximab then Cetuximab (initial dose 400 mg/m²)

(250 mg/m²/week x 6) (250 mg/m²/week x 4)

Recurrent or metastatic head and neck, performance status 0 or 1

ECOG E1305

Physician choice of chemotherapy regimens

Cisplatin doublet vs Cisplatin-doublet + Bevacizumab
LEUKEMIA

Previously treated relapsed or refractory chronic lymphocytic leukemia  Phase II .......................................................... ECOG E2903

IRB review pending -- Can be expedited upon request
Rituximab + Pentostatin + Cyclophosphamide
then
if complete or nodular partial remission: Campath-1H (30 mg sc TIW x 4 wks)
or
if partial remission or less than partial remission or progressive disease: Campath-1H (30 mg sc TIW x 18 wks)

LYMPHOMA

*** Untreated diffuse large B-cell lymphoma -- fresh (frozen) tumor biopsy must be available............................................. CTSU CALGB-50303
R-CHOP vs DA-EPOCH-R

MELANOMA

*** Unresectable stage III or IV melanoma; ≤ 1 prior systemic therapeutic regimen......................................................... ECOG E1608
Cycles 1-4: GM-CSF (d1-14) + Ipilimumab (d1) then Cycles ≥ 5: GM-CSF (d1-14) + Ipilimumab (d1 every 4th cycle)
vs
Cycles 1-4: Ipilimumab (d1) then Cycles ≥ 5: Ipilimumab (d1 every 4th cycle)

MDS

Low- or Intermediate-1 Risk MDS and Symptomatic Anemia.......................................................................................... ECOG E2905
Del 5q31.1: Arm A -- Lenalidomide until relapse/progression/no MER then cross over to Arm B
Not Del 5q3.1: Arm A -- Lenalidomide until relapse/progression/no MER then cross over to Arm B or
Arm B -- Lenalidomide + epoetin alfa until relapse/progression

MULTIPLE MYELOMA

Newly diagnosed multiple myeloma – not candidates for high-dose therapy..................................................................... ECOG E1A06
Per IRB Approval: “...any male or female that does not have to be started on birth control can be enrolled into the study…”
Melphalan + Prednisone + Thalidomide + Aspirin vs Melphalan + Prednisone + Lenalidomide + Aspirin
then
Thalidomide maintenance
then
Lenalidomide maintenance

THORACIC - SMALL CELL LUNG CANCER

Extensive Stage SCLC......................................................................................................................................................... ECOG E1508
Cisplatin + Etoposide (4 cycles) then observation
vs
Cisplatin + Etoposide + GDC-0449 (4 cycles) then GDC-0449
vs
Cisplatin + Etoposide + IMC-A12 (4 cycles) then IMC-A12

THORACIC - NON-SMALL CELL LUNG CANCER

Stage 1 NSCLC, mass ≥ 2.0cm and ≤ 6.0cm in diameter on CT -- patient must consent prior to surgery............. CTSU CALGB-30506
Observation
vs
Physician choice: Maximum 4 cycles of cisplatin + (vinorelbine, docetaxel, gemcitabine, or premetrexed)
Unresectable Stage IIIA/B non-squamous NSCLC without significant pleural effusion -- Phase II..........................ECOG E6508
Paclitaxel + Carboplatin for 2 cycles + RT for 6.5 wks
then if no disease progression
Paclitaxel + Carboplatin for 2 cycles
then if no disease progression
Cyclophosphamide + Bevacizumab + L-BLP25 vaccine up to maximum of 34 cycles

NSCLC and N₀-- <2cm peripheral & outer third...........................................................................................................CTSU CALGB-140503
Lobectomy vs Limited Resection

Stage IIIB or IV or recurrence after prior curative resection or definitive RT and non-smoker (≤ 100 cigarettes in lifetime)..............................................................ECOG E2508
Placebo daily + Paclitaxel + Carboplatin + Bevacizumab(if eligible) for 6 cycles then Placebo +/- Bevacizumab
vs
Erlotinib daily + Paclitaxel + Carboplatin + Bevacizumab(if eligible) for 6 cycles then Erlotinib +/- Bevacizumab

Completely resected stage IB-IIIA NSCLC................................................................................................................ECOG E1505
Physician choice of: cisplatin + (vinorelbine, docetaxel, gemcitabine, or premetrexed)
vs
Physician choice of the above therapies + Bevacizumab

Advanced non-squamous NSCLC Suspended........................................................................................................ECOG E3508
Paclitaxel + Carboplatin + Bevacizumab on day 1 of 6 cycles then if no PD Bevacizumab until PD
vs
Paclitaxel + Carboplatin + Bevacizumab + IMC-A12 x 6 cycles then if no PD Bevacizumab + IMC-A12 until PD
(d1) (d1) (d1) (d 1,8,15) (d1) (d 1,8,15)

Advanced NSCLC who will not receive Bevacizumab -- suspended..............................................................ECOG E4508
Standard Chemo + Cetuximab cycles 1-2 then Cetuximab cycles 3 and on
vs
Standard Chemo + IMC-A12 cycles 1-2 then IMC-A12 cycles 3 and on
Vs
Standard Chemo + Cetuximab + IMC-A12 cycles 1-2 then Cetuximab + IMC-A12 cycles 3 and on

Maintenance tx following initial 4 cycles of chemo in stage IIIB/IV NSCLC..................................................CTSU CALGB-30607
Sunitinib vs Placebo

***Denotes newly activated study
^^^Denotes listing updated due to amendments made to the trial