

## **ACTIVE CANCER CLINICAL TRIALS**

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#### **Clinical Trials Nurses**

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#### **Closures:**

- **ECOG E1A06** - Newly diagnosed multiple myeloma – not candidates for high-dose therapy -- *Trial reached accrual goal*
- **CALGB 40502** - Locally recurrent or metastatic, first-line -- *Results of a planned interim analysis of the primary endpoint of progression-free survival indicated that it is very unlikely that therapy with nab-paclitaxel (with or without bevacizumab) will be better than paclitaxel (with or without bevacizumab).*

## BRAIN CANCER

Newly diagnosed glioblastoma or gliosarcoma..... RTOG-0837  
*IRB review pending -- Can be expedited upon request.*  
ChemoRT + Temozolomide + Cediranib vs ChemoRT + Cediranib +Placebo

## BREAST CANCER

\*\*\*Early-stage resected by lumpectomy..... RTOG-1005

*IRB review pending -- Can be expedited upon request.*

Standard fractionation	vs	Hypofractionation (15 fractions total)
Whole breast 50.0 Gy/25 fractions/2.0 Gy daily		Whole breast 40 Gy/15 fractions/2.67 Gy daily
Optional fractionation of 42.7 Gy in 16 fractions		Concurrent boost 48.0 Gy/3.2 Gy daily
Sequential Boost 12.Gy/6 fractions/2.0 Gy daily		
or 14.0Gy/7fractions/2Gy daily		

Resected node-positive or high-risk node-negative HER2-Low Invasive..... NSABP B-47

*IRB review pending -- Can be expedited upon request.*

Physician choice of chemo:

TC *or* AC→ weekly paclitaxel  
then chemo vs chemo + (trastuzumab for 1 yr)

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

≤ 84 days from mastectomy, axillary dissection or sentinel node detection

Adriamycin/Cytosan + Pegfilgrastim (q 2 wks x 4)	then	Taxol + Pegfilgrastim (q 2 wks x 6)
(60mg/m <sup>2</sup> ) (600mg/m <sup>2</sup> )		(175mg/m <sup>2</sup> )
vs		

Adriamycin/Cytosan + Pegfilgrastim (q 2 wks x 4)	then	Taxol (q wk x 12)
(60mg/m <sup>2</sup> ) (600mg/m <sup>2</sup> )		(80mg/m <sup>2</sup> )

## GASTROINTESTINAL MALIGNANCIES - ESOPHAGEAL

Esophageal cancer treated without surgery; ≥ 18 and < 75 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

Her2-Positive, adenocarcinoma of esophagus involving mid, distal and/or esophagogastric junction ..... RTOG 1010

*IRB review pending -- Can be expedited upon request.*

*Must send out ICH*

RT + paclitaxel + carboplatin + trastuzumab then sy 5-8 wks after RT then trastuzumab q3wk x 13  
vs

RT + paclitaxel + carboplatin then sy 5-8 wks after RT

## GASTROINTESTINAL MALIGNANCIES - PANCREAS

\*\*\*Locally advanced or metastatic pancreatic neuroendocrine tumor ..... CTSU CALGB-80701

*IRB review pending -- Can be expedited upon request.*

Everolimus + Octreotide vs Everolimus + Bevacizumab + Octreotide

## 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.*

Irinotecan + Cetuximab every 2 wks vs Irinotecan + Cetuximab + Ramucirumab (IMC-1121B) every 2 wks

### GASTROINTESTINAL MALIGNANCIES – COLON OR RECTUM

**Metastatic colon or rectum, *KRAS normal (wild type) only*** ..... CTSU CALGB-80405  
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** ..... CTSU CALGB-90802  
Everolimus + Placebo vs Everolimus + Bevacizumab

### GENITOURINARY – BLADDER

**Metastatic or unresectable transitional cell carcinoma of urinary tract** ..... CALGB 90601  
Gemzar + Cisplatin + Placebo vs Gemzar + Cisplatin + Bevacizumab

**Muscle-invasive bladder cancer, non-cystectomy candidates, *Phase I/II -- Suspended*** ..... CTSU RTOG-0524  
*Her2/neu overexpression:*  
RT + Paclitaxel + Trastuzumab  
*No her2/neu overexpression:*  
RT + Paclitaxel

### GENITOURINARY – PROSTATE

**Prostate cancer metastatic to bone** (no prior bisphosphonate or radiopharmaceuticals) ..... CTSU CALGB-90202  
*IRB review pending -- Can be expedited upon request.*  
Zoledronic Acid vs Placebo

**Prevention of Erectile Dysfunction - stage T<sub>1b</sub>-T<sub>2b</sub>, M<sub>0</sub>** ..... RTOG-0831  
*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** ..... CTSU-GOG-0252  
**Stage II, III, or IV with either optimal ( $\leq 1$  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 intraperitoneal day 1 + Bevacizumab day 1 beginning cycle 2  
vs  
Paclitaxel 135mg/m IV day 1 + Cisplatin 75mg/m<sup>2</sup> intraperitoneal day 2 + Paclitaxel 60mg/m<sup>2</sup> intraperitoneal day 8  
+ Bevacizumab day 1 beg cyc 2  
**Cycles 7 - 22 for all arms:**  
Bevacizumab day 1

## HEAD AND NECK

**HPV-associated oropharynx  $T_{1-2}N_{2a-3}$ ,  $T_{3-4}$  any N** ..... RTOG 1016  
**IRB review pending -- Can be expedited upon request**  
Mandatory p16 analysis by OSU lab after pt. consent & before randomization  
IMRT + high dose cisplatin vs IMRT + cetuximab  
x6 wks d 1,22 x6wks x6 wks 8 doses (1 prior to chemoXRT & 1 following chemoXRT)

**Locally-advanced resected head and neck cancer -- Gross total resection of tumor; no prior chemo** ..... RTOG 0920  
 $T_1N_{1-2}M_0$ ,  $T_{2-3}N_{0-2}M_0$ ,  $T_3$ , Microscopic  $T_{4a}$   
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/m<sup>2</sup>) (250 mg/m<sup>2</sup>/week x 6) (250 mg/m<sup>2</sup>/week x 4)

**Recurrent or metastatic head and neck, performance status 0 or 1** ..... ECOG E1305  
Physician choice of chemotherapy regimens  
Platinum-doublet vs Platinum-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

**High risk follicular lymphoma** ..... ECOG E2408  
**IRB review pending -- Can be expedited upon request**  
Rituximab + Bendamustine x 6 cycles then Rituximab  
vs  
Rituximab + Bendamustine + Bortezomib x 6 cycles then Rituximab  
vs  
Rituximab + Bendamustine then Lenalidomide + Rituximab

## MELANOMA

**High risk completely resected melanoma - no prior adjuvant tx** ..... ECOG E1609  
**IRB review pending -- Can be expedited upon request**  
Randomize within 84 days of resection  
Ipilimumab (10mg/kg) then maintenance vs Interferon Alfa-2b then maintenance  
q3wks x 4 qwk x 4

## 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

**THORACIC - NON-SMALL CELL LUNG CANCER**

**Stage 1 NSCLC, mass  $\geq$  2.0cm and  $\leq$  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 N<sub>0</sub> -- <2cm peripheral & outer third.....** CTSU CALGB-140503

Lobectomy vs Limited Resection

**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.....** 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)

\*\*\*Denotes newly activated study