

**CRO Communiqué**  
**Keeping you informed about CRO progress**  
**April, 2011**

**Top Enrolling Physicians for grant year 6/1/2010 – 5/31/2011**

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bonebrake	18	16	1	17
Dr. Williams	14	12	2	14
Dr. Ellis	12	9	2.5	11.5
Dr. Raju	10	3	5.5	8.5

Fourteen new patients went on trial in March at CRO sites. Dr. Helen Kim had three this month placing three patients on N0841 before it closed. Dr. Bonebrake continues to lead the race with 18 registrations earning 17 NCI credits this grant year. Currently, we have 91.4 treatment credits, 8.6 credits below where we need to be to meet NCI's target credit of 120 for this grant year. We have earned 47.7 cancer control credits. We need to be at 58.3 to be on target to meet the NCI assigned target credit of 70 for this grant year. The remaining two months of our grant year must be strong for us to meet our target credits. Thank you for offering clinical trials to each of your patients.

**Study Profile for February- March**

**SWOG S1007** "A Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer With Recurrence Score (RS) of 25 or Less" is our study to profile this month. Patients must not have inflammatory breast cancer and must not have metastatic disease. Patients must have Recurrence Score (RS) by Oncotype DX® of  $\leq 25$ . Registration must take place within 84 days after definitive surgery. Patients must not have begun chemotherapy or endocrine therapy for their breast cancer prior to randomization.

**March 28<sup>th</sup> Steering Committee Meeting**

Thirty-seven physicians and research staff attended the CRO Steering Committee meeting on Monday, March 28 at TOUCH Restaurant. Dr. Carolla gave an update of CRO activities. Dr. Brian Barnett gave an interesting presentation on Adjuvant HER2 Breast Cancer Therapy with Herceptin. Dr. Barnett serves as Director of Medical Oncology at the Elliott, Elliot, Head Breast Cancer Center in Baton Rouge, Louisiana and previously served as an Assistant Professor at Tulane University Medical Center. Dr. Barnett has an interest in translational research and served as co-investigator in numerous tumor immunotherapy clinical trials while at Tulane. Genentech sponsored the event. A nice educational evening was had by all attending.

**Research Bases Joining**

The American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), and North Central Cancer Treatment Group (NCCTG), which are National Cancer Institute (NCI) funded cancer cooperative groups, today announced plans to merge. "The three groups will create one integrated cooperative group that will develop and conduct more efficient clinical research strengthen and streamline operations among NCI clinical trials cooperative group programs," says Jan Buckner, M.D., NCCTG group chair, professor of oncology, and chair of the Division of Medical Oncology at Mayo Clinic in Rochester, Minn. This announcement reflects the call in April 2010 from the Institute of Medicine to decrease the number of adult cooperative groups from nine to four.

**Possible New CRO Affiliate**

CRO has been approached by oncologists working at Phelps County Regional Hospital in Rolla for a possible affiliation to offer CRO trials to their patients. Dr. Bond and Dr. Nevils met with Dr. Carolla and Marilyn Bauer on Monday, March 31, 2011 to explore this possibility. Follow-up efforts are being explored with administration at Phelps County at this time.

## **New Studies Approved in March 2011**

### **Opened at Cox and St. John's**

**GOG 0186G** A Randomized Phase II Evaluation of Everolimus (RAD001) plus Bevacizumab VS. Oral Placebo plus Bevacizumab in the Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**SWOG S1007** A Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer With Recurrence Score (RS) of 25 or Less

### **Opened at Cox Only**

**CTSU CALGB 30607** Randomized, Phase III, Double-Blind Placebo-Controlled Trial of Sunitinib (NSC #736511, IND #74019) 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

**RTOG 0617** A Randomized Phase III Comparison of Standard-Dose (60 Gy) Versus High-Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel +/- Cetuximab (IND #103444) in Patients With Stage IIIA/IIIB Non-Small Cell Lung Cancer

### **Opened at St. John's Only**

**GOG 0260** A Phase II Evaluation of Elesclomol Sodium and Weekly Paclitaxel in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian, Fallopian Tube or Primary Peritoneal Cancer

**NSABP B-47** A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Doctaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer

**RTOG 0724** Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy

### **Studies Closed March 2011 :**

**CTSU 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

**CTSU ECOG E5202** A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers

**GOG 0127V** A Phase II Evaluation of ABI-007 in the Treatment of Persistent or Recurrent Squamous or Non Squamous Cell Carcinoma of the Cervix (Abraxis BioScience, LLC Study)

**SWOG S0424** Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men

**RTOG 0841** Efficiency of Screening for Depression in Cancer Patients Receiving Radiotherapy

**RTOG 0517** Randomized Phase III Trial To Evaluate Radiopharmaceuticals And Zoledronic Acid In The Palliation Of Osteoblastic Metastases From Lung, Breast, And Prostate Cancer

**NCCTG N08C2** A Pilot Phase II, Randomized, Double Blind Trial of Palonesetron versus Placebo to Prevent Radiation Therapy Induced Nausea and Vomiting

**CALGB 170601** A Phase III Double Blind Trial of Oral Duloxetine for Treatment of Pain Associated with Chemotherapy-Induced Peripheral Neuropathy (CIPN)