

## CRO Communiqué

### Keeping you informed about CRO progress January 2016

### Top Enrolling Physicians for December 2015

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Registered Exceptional Responders	Tissue Procurement Phase II
Dr. Bechtel (Mercy St. Louis)	1		1	1		
Dr. Finnie (Mercy St. Louis)	1	1		1		
Dr. Gillette (Cox)	1	0.41		0.41		
Dr. Hanson (Mercy St. Louis)	2					
Dr. Huq (Mercy St. Louis)	1	1	0.25	1.25		
Dr. Sleckman (Mercy St. Louis)	1	1	0.25	1.25		
Dr. Spencer (Phelps)	1		1	1		
Dr. Tiriveedhi (Mercy Springfield)	1	1		1		
<b>TOTALS</b>	9	4.41	2.5	6.91		

Low accruals continue to be an increasing concern for our NCORP. CRO earned only 6.9 credits with 9 registrations in December. There were no new exceptional responders approved and no tissue procurements collected for the Phase II of this initiative. NCI's target accrual for CRO this year is 170 credits. To achieve this we must average 14.17 credits each month. Five months into our current grant year CRO has earned 39.31 credits. To be on track to meet our 170 credit target goal we need to be at 70.83 credits. Please continue to make every effort to place our patients on a clinical trial.

#### **CRO Website Update**

An update to CRO's website will start in January. We hope to make our website more interactive and user friendly for our investigators and community members. Please review our current site at <http://ozarkscancerresearch.org> and send any suggestions you would like to see considered to [Marilyn.Bauer@CoxHealth.com](mailto:Marilyn.Bauer@CoxHealth.com)

#### **Revisions to S1400 "Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer"**

This trial has been modified with FDA approval of nivolumab, the S1400 trial will now offer a new nivolumab versus nivolumab+ipilimumab sub-study. The revised design also turns three biomarker-driven sub-studies into single arm Phase II trials testing targeted treatments for advanced squamous cell lung cancer, aiming to find early signals of efficacy. Prior docetaxel use is no longer an exclusion criteria, which will allow many more patients to enroll. And patients can now pre-screen for the trial during any line of their treatment. That means that if first-line therapy fails -- as it unfortunately does in most cases -- patients have an immediate treatment "Plan B." These changes bring a continuing bright future for Lung-MAP. It's special. With its cutting-edge "master protocol" design, Lung-MAP gives us significant bang for our buck, offering four trials in one and offering a large percentage of advanced squamous patients a study treatment option.

#### **NCORP Clinical Trial Screening Tool**

NCI has announced an NCORP screening tool entitled, "DCP-001: Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP). Staff will need to complete the 20 question demographic tool for patients screened who do not go on trial. Each enrollment is worth 0.02 credits. NCI will be holding training webinars in January and plan to launch this new effort in January as well.

#### **Cardiotoxicity Article: Treating Cancer without Harming the Heart**

An article focusing on efforts towards cardiotoxicity research was recently posted on the NCI website (<http://www.cancer.gov/about-cancer/treatment/research/cardiotoxicity>) and is also posted on the NCORP public website (<http://ncorp.cancer.gov/>). This article provided information pertaining to efforts being undertaken between the NCI and National Heart, Lung and Blood Institute. NCORP, and its involvement in

past and current research trials, is addressed in the article. A currently active cardiotoxicity trial that NCORPs should be aware of is the PREVENT study (Wake Forest 98213) and a soon to be available trial, SWOG S1501.

### **MATCH Screening Efforts – Share Your Thoughts**

NCORPs are being invited to share their experiences with screening and enrolling patients to the precision medicine trials such as MATCH. Comments received have included issues regarding the time associated with screening has taken time away from accrual to other trials, start up efforts have been significant, the trials are difficult to explain to staff and patients, the ratio of credits to accruals is low, and the credit volume does not reflect the effort. During the “pause” phase of the MATCH trial NCI will be evaluating multiple factors associated with the precision medicine trials. If you have other or similar issues/experiences please send them via email to Marge at [goodmj@mail.nih.gov](mailto:goodmj@mail.nih.gov)

### **CIRB Trials Opened in December**

**ECOG-ACRIN EA2142** Randomized Phase II Study of Cisplatin and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas

**NRG-CC003** A Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer

### **Temporary Closures in December**

**NRG GY001** A Phase II Trial of Cabozantinib (XL-184) (NSC #761968) in Women with Recurrent, Clear Cell Carcinoma of the Ovary, Fallopian Tube, or Peritoneum – Temporary closure effective 11/30/2015

**SWOG S1406** Randomized Phase II Study of Irinotecan and Cetuximab with or Without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer – Temporary closure effective 12/23/15

### **Permanent Closures in December**

**Alliance A041202** A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients ( $\geq$  65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) – Closed to accrual 12/28/2015

**ECOG-ACRIN E2607** A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Vulvovaginal Melanomas – Closed to accrual 12/29/2015

### **SUB-STUDY OPENING:**

**SWOG S1400I** A Phase III Randomized Study of Nivolumab Plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker Initial Activation December 18, 2015

### **SUB-STUDY CLOSURE:**

**SWOG S1400A** A Phase II Study of MEDI4736 for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarkers (LUNG-MAP SUB-STUDY) – Closed to accrual 12/18/2015

**SWOG S1400B, S1400C, & S1400D** Partial Permanent Closure to Arm 2- Docetaxel – 12/18/2015

**Happy New Year to you! We are looking forward  
to a year of many clinical trial enrollments.**

**From the Staff at Cancer Research for the Ozarks**

