

# CRO Communiqué Keeping you informed about CRO progress March 2016

# **Top Enrolling Physicians for February 2016**

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	Patient	Treatment	Control	Total	Exceptional	Procurement
Physician	Registrations	Credits	Credits	Credits	Responders	Phase II
Dr. Bechtel (Mercy St. Louis)	1	0.1		0.1		
Dr. Bonebrake (Cox)	4					4
Dr. Bumberry (Mercy Springfield)	1		1	1		
Dr. Creach (Mercy Springfield)	1		1	1		
Dr. Ding (Cox)	1					1 – blood only
Dr. Ellis (Cox)	2	1.04		1.04		1
Dr. Estes (Mercy Springfield)	1	1.08	0.25	1.33		
Dr. Gillett (Cox)	1	0.31		0.31		
Dr. Pinheiro (Mercy Springfield)	1					1
Dr. Tiriveedhi (Mercy Spfld)	1	0.34		0.34		
TOTALS	15					6 + 1blood
		2.87	2.25	5.12		only

CRO earned only 5.12 credits from in February. Six tissue plus blood and 1 blood only specimens were obtained for our Phase II tissue procurements. NCI's target accrual for CRO this year is 170 credits. To achieve this we must average 14.17 credits each month. Please continue to make every effort to place our patients on a clinical trial. Our enrollments have never been this low in my 10 years of being here.

#### PALLAS Trial - CRO's Profile Study

PALLAS "PALbociclib CoLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+) / Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer" is going to the IRB on March 17th. This is a prospective, two arm, international, multicenter, randomized, open-label Phase III study evaluating the addition of 2 years of palbociclib to standard adjuvant endocrine therapy for patients with HR+ / HER2- early breast cancer (EBC). The purpose of the PALLAS study is to determine whether the addition of palbociclib to adjuvant endocrine therapy will improve outcomes over endocrine therapy alone for HR+/HER2- early breast cancer. Assessment of a variety of correlative analysis, including evaluation of the effect of palbociclib in genomically defined tumor subgroups, is planned. CRO sites opening this trial include CoxHealth, Mercy Springfield, Mercy St. Louis and Phelps County. This trial is an Alliance Foundation trial and no other sites can participate at this time. CRO has requested notification if additional sites should open.

## **Spring 2016 CRO Steering Committee Meeting**

Dr. Montaser Shaheen, from the University of New Mexico Cancer Center will be our speaker for our April 4, 2016 Steering Committee Meeting. The title of his presentation is "An Immuno-Oncology Agent Approved Across Multiple Tumor Types, Opdivo(nivolumab), A Renal Cell and Lung Carcinoma Overview". Invites will be coming out soon. Please mark your calendars to attend.

#### **SWOG Mentoring Workshop**

CRO staff were invited by the Wichita NCORP to join them for a SWOG Mentoring Workshop in Wichita on Wednesday, February 17<sup>th</sup>. Debbie Cane and Marilyn Bauer attended the Mentoring Workshop Session. This was a great opportunity for our staff to network with the Wichita staff while receiving some great updates from the SWOG staff.

#### **Brandy Cook**

Welcome to Brandy Cook who is the new Cancer Research Professional at Good Samaritan in Mt. Vernon, Illinois. Brandy has a BS with experience working in the hospital laboratory phlebotomy/pathology department. Welcome Brandy!

#### **Connie Roller**

Welcome to Connie Roller who joined CRO as our long-term follow up CRA on February 22<sup>nd</sup>. We are delighted to have Connie on board with us at the CRO Administrative Office. Connie previously was the office manager at a single physicians practice and is well prepared to do our long term follow-ups, oversee our pharmacy and complete other tasks.

#### **Trials Opened in February at Local IRB**

<u>WAKE FOREST WF 97115:</u> A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer

### **Temporary Closures in February- CIRB Trials**

ECOG-ACRIN EA6134 A Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab Followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma

Temporarily closed to accrual effective 2/2/2016

**ECOG-ACRIN EAY131** Molecular Analysis for Therapy Choice (MATCH) *Sub protocols H & R Temporary closed to accrual effective 2/2/2016* 

<u>GOG-0281</u> A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer *Temporarily closed to accrual effective* 2/2/2016

<u>RTOG 1216</u> Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin versus Docetaxel versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of the Head and Neck

Temporarily closed to accrual effective 2/22/2016

SWOG S1320 A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAF V600E/K Mutant Melanoma *Temporarily closed to accrual effective 2/2/2016* 

#### Permanent Closures in February - CIRB Trials

<u>RTOG 0815</u> A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer *Closed to accrual effective 3/7/2016*