

## CRO Communiqué

### Keeping you informed about CRO progress

#### April 2014

#### **Top Enrolling Physicians for March 2014**

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Braun (Mercy Spfld.)	1	1	0.5	1.5
Dr. Carlson (Mercy Spfld)	1	0	1	1
Dr. Ellis (Cox)	2	2	0.9	2.9
Dr. Hanson (Mercy St. Louis)	1	2	0	2
Dr Raju (Mercy Spfld)	3	3.1	1	4.1
Total	8	8.1	3.4	11.5

Enrollments continue to be slow. We earned 11.5 credits for March plus 0.2 follow-up credits. This gives us 166.2 credits for this grant year. We need to earn 33.8 additional credits by May 31, 2014 to meet the 200 credits required for additional funding with the NCORP grant. Please be diligent with screening and placement of patients on CRO studies. We still have time to reach our goal of 200 credits with everyone pulling together.

#### **Status of the CCOP NCORP Program Transition**

During the past week, NCI told us,

- All CCOP funding will end on May 31, 2014, not just those like CRO whose 5-year grant period ends.
- The NCORP program is scheduled to begin on September 1, 2014.
- No new cancer control trials will be activated by NCI until NCORP begins. New Treatment trials will continue to be activated.
- There will be a funding gap for the months of June, July and August 2014.
- Several funding options are available for CRO. Our Executive Board will be reviewing our options and making the decision best for CRO.

It sounds as if they will notify sites as they are eliminated from the NCORP grant process. So, no news is good news.

#### **Profile Study**

**E1912** “A Randomized Phase III Study of Ibrutinib (PCI- 32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)” is our profile study. This randomized phase III trial studies ibrutinib and rituximab to see how well they work compared to fludarabine phosphate, cyclophosphamide, and rituximab in treating patients with untreated chronic lymphocytic leukemia or small lymphocytic lymphoma. Ibrutinib may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Drugs used in chemotherapy, such as fludarabine phosphate and cyclophosphamide, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Monoclonal antibodies, such as rituximab, can block cancer growth in different ways. Some block the ability of cancer to grow and spread. Others find cancer cells and help kill them or carry cancer-killing substances to them. It is not yet known whether fludarabine phosphate, cyclophosphamide, and rituximab are more effective than ibrutinib and rituximab in treating patients with untreated chronic lymphocytic leukemia or small lymphocytic lymphoma.

#### **CRO Steering Committee**

We will have a CRO Steering Committee meeting on Thursday, May 15<sup>th</sup>. Kelly McCaul, MD, Director of the Avera Hematology and Transplant Program in Sioux Falls SD will speak to us on “A New Treatment Option in Previously Treated Chronic Lymphocytic Leukemia and Mantle Cell Lymphoma”. Please mark your calendars to join us at TOUCH restaurant at 6pm on Thursday, May 15<sup>th</sup>.

#### **New CRO Research Nurse**

Michelle McKenzie joined CRO staff on Monday, March 3<sup>rd</sup>. Welcome Michelle! Michele comes to CRO from outpatient chemo at Hulston Cancer Center and is OCN certified.

## **New Studies Approved in March, 2014 Through Cox's IRB**

ECOG E1412 "Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients With Newly Diagnosed Diffuse Large B Cell Lymphoma"

SWOG S1222 "Fulvestrant Alone Versus Fulvestrant and Everolimus Versus Fulvestrant, Everolimus and Anastrozole: A Phase III Randomized Placebo-Controlled Trial In Postmenopausal Patients With Hormone-Receptor Positive Stage IV Breast Cancer"

## **New Studies Approved and Opened in March with the CIRB**

Alliance A091105 "A Phase III, Double Blind, Randomized, Placebo-Controlled Trial of Sorafenib in Desmoid Tumors or Aggressive Fibromatosis (DT/DF)"

ECOG E1912 "A Randomized Phase III Study of Ibrutinib (PCI- 32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)"

GOG-0286B "A Randomized Phase II/III Study Of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo As Initial Therapy For Measurable Stage III Or IVA, Stage IVB, or Recurrent Endometrial Cancer"

ECOG E2906 "A Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age Greater Than or Equal to 60 Years)"

SWOG S1203 "A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7+3) Therapy of Idarubicin with High Dose Cytarabine (IA) Untreated Acute Myeloid Leukemia (AML)"

## **Studies sent to Cox & Mercy IRB's for Permanent Closure in March 2014**

GOG 0235 "A Prospective, Longitudinal Study of YKL-40 in Patients with FIGO Stage III or IV Invasive Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer Undergoing Primary Chemotherapy"

SWOG OV.21 "A Phase II/III Study of Intraperitoneal (IP) Plus Intravenous (IV) Chemotherapy Versus IV Carboplatin Plus Paclitaxel in Patients with Epithelial Ovarian Cancer Optimally Debulked at Surgery Following Neoadjuvant Intravenous Chemotherapy"

RTOG 0622 "A Phase II Trial of Samarium 153 Followed by Salvage Prostatic Fossa 3D-DRT or IMRT Irradiation in High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy"