NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

CRO Communiqué
Keeping you informed about CRO Progress

Cancer Research for the Ozarks

February 2017
Enrolling Physicians for January 2017

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Tissue Procurement	Cancer Care Delivery Res.
Dr. Bonebrake (Cox)	GOG-3005 - 1		0.1375	0.1375		
Dr. Carlson (Mercy Spfld)	GOG-3005 - 1	.775		.775		
Dr. Cunningham (OHA)			0.0125	0.0125		
Dr. Ellis (OHA)			0.0125	0.0125		2
Dr. Gillette (OHA)			0.0250	0.0250		3
Dr. Hanson (Mercy St. Louis)	2	2.1		2.1		
Dr. Hawamdeh				.0125		
Dr. Huq (Mercy St. Louis)	1	1.15	.25	1.4		
Dr. Kosuri (Mercy St. Louis)	1 + PALLAS	1.00		1.0		
Dr. Nair (Mercy Spfld)			0.0125	0.0125		1
Dr. Shah (Mercy St. Louis)		0.4625		.4625		
Dr. Snider (Mercy Spfld)		.25	0.1750	0.4250		4
Dr. Tiriveedhi (Mercy Spfld)	1	1.15	.25	1.4		
Dr. Toothaker (Phelps)	1		0.3125	0.3125		
Dr. Tummala (Mercy Spfld)			0.0375	0.0375		3
Dr. Verma (Cox)	1	1.05		1.05		
TOTALS	7	7.9375	1.2375	9.175		13

CRO has done well with enrollments to our open CCDR study (S1415CD) with 13 enrolled during January. We have 23 enrolled at Mercy Springfield and 8 at OHA for this trial. 52 are to be enrolled at each site. We are still behind on our credits half way through the grant year. CRO has earned 46.5375 credits and need to be at 80 credits to meet NCI's credit goal for us this grant year. This is 58.17% of where we need to be. All efforts to place our patients on a clinical trial are appreciated.

Institutional Review Board Changes

Mercy Research is in the process of moving all studies from all Mercy locations doing research within the Mercy system to a single Mercy Institutional Review Board (MIRB). The function of the Mercy Institutional Review Board will be to review the Investigator Initiated Trial (IIT), Humanitarian Use Device (HUD), and Compassionate use (CU) studies. Mercy's IRB board will consist of nine representatives from all Mercy areas serving on a single virtual board. Mercy hopes is to have the Mercy Institutional Review Board functioning by late March. Mercy will be using both an outside central review board and the Mercy Central Board. CRO will continue to use the NCI CIRB for NCI trials and MIRB or an outside IRB as deemed necessary.

S1418/BR600 Profile Study

A Randomized Phase III Trial to Evaluate Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with >/=1 CM Residual Invasive Cancer or Positive Lymph Nodes (>ypN+) After Neoadjuvant Chemotherapy is our profile study this month. This randomized phase III trial studies how well pembrolizumab works in treating triple-negative breast cancer. Monoclonal antibodies, such as pembrolizumab, may interfere with the ability of tumor cells to grow and spread. One experimental: Arm I (observation) patients receive no treatment but are monitored at standard clinical intervals during first year after randomization. Patients are examined every 12 weeks for 1 year, every 6

months for 4 years, and then annually for 5 years. Patients may undergo radiation therapy within 12 weeks of last breast cancer operation or after treatment. On experimental: Arm II (pembrolizumab) patients receive pembrolizumab IV over 30 minutes on days 1 and 22. Courses repeat every 42 days for 52 weeks in the absence of disease progression or unacceptable toxicity. Patients may undergo radiation therapy within 12 weeks of last breast cancer operation or after treatment. 1,000 patients are being sought to participate in the trial.

ACTIVATION OF CIRB Protocols:

New Local Protocols:

None

CIRB Protocols:

ECOG-ACRIN EA8143 "A Phase 3 Randomized Study Comparing Perioperative Nivolumab Vs. Observation In Patients With Localized Renal Cell Carcinoma Undergoing Nephrectomy

NRG-GU002 "Phase II-IIII Trial Of Adjuvant Radiotherapy And Androgen Deprivation Following Radical Prostatectomy With Or Without Adjuvant Docetaxel

SWOG S1418 A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with > 1 cm Residual Invasive Cancer or Positive Lymph Nodes (>pN1mic) After Neoadjuvant Chemotherapy

SWOG S1602 Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer

Study Closure through Local IRB:

ECOG-ACRIN 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 – Closed to accrual 01/17/2017.