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

March 2017
Enrolling Physicians for February 2017

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Tissue Procurement	Cancer Care Delivery Res.
Dr. Bechtel	1	1		1		
Dr. Bonebrake (Cox)	1 - GOG-3005				1	
Dr. Carlson (Mercy Spfld)	1 - GOG-3005 + 2	2.5625		2.5625		
Dr. Ding (OHA)			0.0250	0.0250		1
Dr. Donegan (Mercy St. Louis)		0.4375		0.4375		
Dr. Ellis (OHA)		0.5250	0.1375	0.6625		
Dr. Hanson (Mercy St. Louis)	1	1.2	0.25	1.45		
Dr. Kosuri (Mercy St. Louis)		0.15	0.25	0.4		
Dr. Miller (Freeman)		0.4375		0.4375		
Dr. Rodgers (Mercy St. Louis)	2 – PALLAS					
Dr. Snider (Mercy Spfld)			0.0125	0.0125		1
Dr. Tiriveedhi (Mercy Spfld)						3
Dr. Verma (OHA)	1	1		1		
TOTALS	5	7.3125	0.675	7.9875	1	5

CRO enrollments have slowed since last month. Every effort to place our patients on a clinical trial is appreciated.

Spring 2017 CRO Steering Committee Meeting

Gary Doolittle MD, Professor of Medicine and Director of Telemedicine Services at The University of Kansas Medical Center will be our speaker for our CRO 2017 Steering Committee meeting. Dr. Doolittle will be speaking on melanoma and head and neck cancer. He has received numerous research grants, authored over 80 journal articles and manuscripts all while practicing and teaching medical oncology at the University of Kansas. Please mark your calendars for Wednesday, May 17, 2017 for this informative presentation. The event will be held at TOUCH Restaurant. More to come on the event.

SWOG S1609 Profile Study

SWOG S1609 DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors This clinical trial studies nivoluman and ipilmumab in treating patients with rare tumors. Patients must have histologically confirmed rare cancer and/or cancer of unknown primary, that did not have a match to a molecularly-guided therapy on EAY131 "National Cancer Institute (NCI)-Molecular Analysis for Therapy Choice (MATCH)" protocol or who progressed on molecularly-matched therapy and have no further molecularly-matched treatment recommendations per EAY131, "NCI-MATCH" Monoclonal antibodies, such as nivoluman and ipilmumab may interfere with the ability of tumor cells to grow and spread. The primary objective is to evaluate the Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 overall response rate (ORR) in subsets of patients with advanced rare cancers treated with ipilimumab plus nivolumab combination immunotherapy. Secondary Objectives are: 1.. To evaluate toxicities in each cohort. II. To estimate overall survival (OS), progression-free survival (PFS), clinical benefit rate; and to estimate immune-related ORR (irORR), and immune-related PFS (irPFS) by unidimensional immune-related response criteria. 2. To collect specimens for banking for use in future correlative biomarker research studies. Patients receive nivolumab intravenously (IV) over 30 minutes on days 1, 15, and 29 and ipilimumab IV over 60 minutes on day 1. Courses repeat

every 42 days in the absence of disease progression or unacceptable toxicity. After completion of study treatment, patients are followed up for 10 years from registration.

Cancer Moonshot Update: Funding Opportunity Announcements

The 21st Century Cures Act, which was signed into law in December 2016, authorizes $1.8 billion over 7 years to fund the Beau Biden Cancer Moonshot[SM]. This additional funding, $300 million of which is available in Fiscal Year 2017, enables NCI to accelerate research efforts aligned with the Cancer Moonshot and build upon the progress that has been achieved over the years. NCI's activities to begin implementing these initiatives include the preliminary step of identifying funding opportunity announcements (FOAs) from within NCI's extensive funding portfolio that aligned with the goals of the Moonshot, and posted these FOAs to NCI's Cancer Moonshot webpage, to simplify the process of searching for funding opportunities that support Cancer Moonshot-related research. The updated list with additional opportunities to mark the beginning of a growing Cancer Moonshot portfolio is posted. Planning for implementation of longer-term scientific initiatives is also underway. Teams have been established to aligned with the BRP recommendations. The teams include NCI extramural and intramural scientists, and experts from several other NIH institutes and centers. Team members are considering multiple ways to fund the best science, including grants, supplements, and other mechanisms, and, where appropriate, to form partnerships with foundations, academia, and the private sector. The support provided by the Cures Act and working together with all of you will enhance NCI's ability to make great strides in transforming the future of cancer research and patient care. Douglas R. Lowy, M.D, Acting Director National Cancer Institute

ACTIVATION OF CIRB Protocols:

New Local Protocols:

None

CIRB Protocols:

ECOG-ACRIN EA2161 "A Phase II Study of MLN0128 (TAK-228) in Rapalog-Resistant Advanced Pancreatic Neuroendocrine Tumors (PNET)"

SWOG S1609 "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors"

Study Closure through Local CIRB:

COG AOST1521 A Phase 2 Study of GPNMB-targeted Antibody-Drug Conjugate, CDX-011 (Glembatumumab Vedotin, CR011-vcMMAE; IND# 128248, NSC# 763737), in Recurrent or Refractory Osteosarcoma

NRG HN002 A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer

Temporary Closure

Alliance A091305 A Phase 2 Randomized Study of Efatutazone, an Oral PPAR Agonist, in Combination With Paclitaxel Versus Paclitaxel in Patients With Advanced Anaplastic Thyroid Cancer