UPMC | HILLMAN CANCER CENTER

CLINICAL RESEARCH SERVICES

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INTRODUCTION

Dear Colleagues,

We would like to welcome you to the first edition of the Clinical Research Services newsletter. This newsletter is part of a concerted effort to increase communication regarding clinical trial activities. Each quarter we plan to share our accrual statistics for the Hillman Cancer Center as well as the community sites. We also plan to highlight some of the trials that are being done so everyone is aware of what is going on across disease groups. We hope that this will be informative, prevent opening of overlapping studies, and help identify areas that need attention. Since we are new at this, we welcome any comments regarding the newsletter. For this effort to have an impact we welcome any feedback whether it is negative or positive. We would also like ideas on what you would like to see included in this publication. We need everyone's help in order to make this a success.

Thank you for your hard work,

Antoinette (Toni) Wozniak
Associate Director of Clinical Research

Bhanu P. Pappu
Vice President of Clinical Operations and Strategy

2018 OPEN STUDIES

Disease Center	Current OTA Trials	Interventional Accruals	Therapeutic Accruals
Biobehavioral	14	252	0
BMT	7	13	13
Brain	12	16	16
Breast	34	117	111
GI/Esophageal	13	46	46
Gynecological	9	25	25
Head and Neck	10	23	23
Hematological	14	53	53
Lung and Thoracic	23	72	39
Melanoma	18	95	95
Pediatric	45	52	48
Phase I	23	65	65
Phase II	37	23	21
Prostate/GU	21	20	20
Radiation	17	70	63
Sarcoma	9	14	14

POINTS OF INTEREST:

Accrual Statistics for 2018

- *Open to Accrual Studies*
- *Top Accruals*
- *Annual Accrual Trends*

Spotlight Trials

- *CDK inhibitor trial in Ovarian Cancer*
- *Immunotherapy IIT in NSCLC*
- *TIL Therapy Trial in Melanoma patients*
- *Combination Therapy in Melanoma*

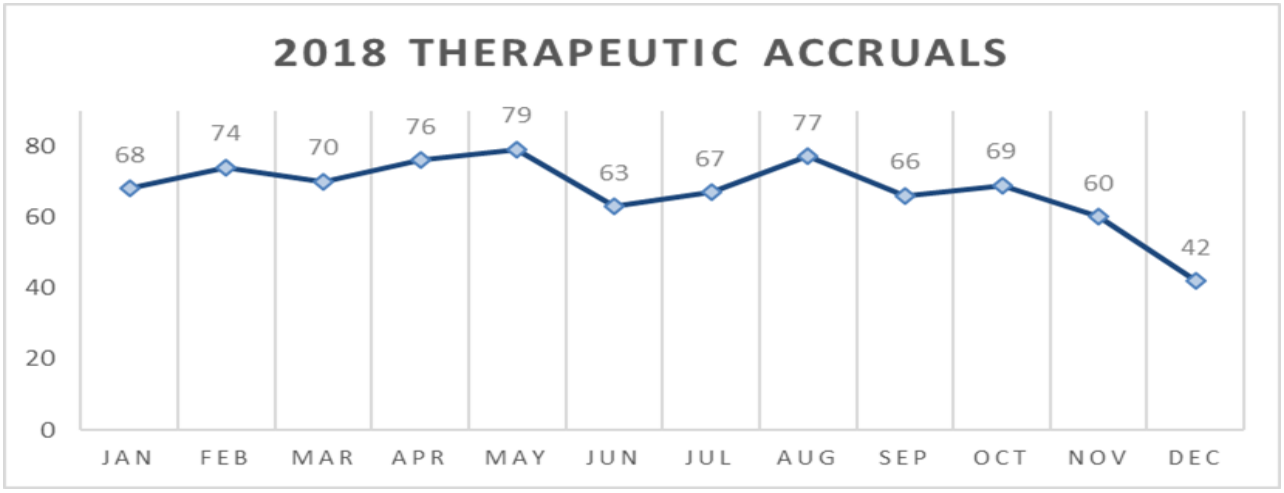
Priority Trials in the Community

- *HER2 Negative Trials*
- *Triple Negative Breast Cancer Trial*
- *Atezolizumab in NSCLC with prior PD-L1 therapy Trial*
- *Prostate Cancer Trial*

TOP THERAPEUTIC ACCRUALS IN 2018

Hillman Cancer Center	Accruals
Diwakar Davar	72
James Ohr	36
Leonard Appleman	31
Adam Brufsky	31
David Clump	27
James Lee	24
Rachel Jankowitz	23
Darrel Triulzi	23
Alison Sehgal	23
John Kirkwood	22
John Rhee	22
Yana Najjar	21
Melissa Burgess	21
Dwight Heron	20
Jan Drappatz	19
(Includes Shadyside, Magee, and Children's)	

Community Network	Accruals
Dhaval Mehta	9
Shannon Puhalla	8
Terry Evans	7
Gauri Kiefer	6
Vincent Reyes	6
Matthew Sulecki	5
Jennifer Osborn	4
Min Sun	4
Mark Georgiadis	3
Gaurav Goel	3
Brian Mclaughlin	3
Rajesh Sehgal	3
Franklin Viverette	3



IIT — RIBOCICLIB IN TREATMENT OF OVARIAN CANCER

Phase I Trial of Ribociclib (LEE-011) with Platinum-based Chemotherapy in Recurrent Platinum Sensitive Ovarian Cancer

HCC# 18-006

The primary objective of this study is to determine the MTD of ribociclib (LEE-011) with platinum + taxane chemotherapy followed by single agent ribociclib maintenance in platinum-sensitive recurrent ovarian cancer. The secondary objective is to determine the response rate and progression free survival of women treated on study.

Ribociclib is an oral cyclin-dependent kinase (CDK) inhibitor targeting cyclin D1/CDK4 and cyclin D3/CDK6 cell cycle pathway approved in breast cancer with potential synergistic antineoplastic activity when used with chemotherapy in ovarian cancer.

Interested physicians can contact Dr. Coffman (PI; coffmanl@mwri.magee.edu) or Ms. Brenda Steele (Manager of Women's Cancer Program, steebx@upmc.edu) with inquiries.

IIT — IMMUNOTHERAPY FOR NSCLC

A phase II clinical trial evaluating the safety and efficacy of durvalumab (MEDI4736) as 1st line therapy in advanced non-small cell lung cancer (NSCLC) patients with Eastern Cooperative Oncology Group (ECOG) performance status of 2

HCC# 16-054, Investigator Initiated Trial

The primary objective of this study is to estimate overall survival (OS) with durvalumab in the upfront treatment of advanced NSCLC patients with an impaired functional status (ECOG Performance status 2).

Durvalumab is an anti-PD-L1 monoclonal antibody that is FDA approved for the treatment of lung cancer in the stage III setting.

Dr. Villaruz recently has expanded this IIT to be a coordinating center for newly added University of Colorado, University of Southern California, Georgetown University, and University of Texas – Southwestern sites. Interested physicians can contact Dr. Villaruz (PI; villaruzl@upmc.edu) or Mr. Daniel Goldstein (Lung Program Manager, goldsteindj@upmc.edu) with inquiries.

IIT — TIL THERAPY FOR MELANOMA

A Phase 2 Study to Evaluate the Efficacy and Safety of Adoptive Transfer of Autologous Tumor Infiltrating Lymphocytes in Patients with Metastatic Uveal Melanoma

HCC# 17-219

The primary objective of this study is to evaluate the efficacy of a non-myeloablative lymphodepleting preparative regimen followed by infusion of autologous TIL and high-dose aldesleukin in patients with metastatic uveal melanoma using the objective response rate (ORR).

Adoptive T cell transfer is a form of immunotherapy that involves the physical repopulation of the host immune system with a selective population of ex vivo expanded T cells. The adoptive transfer of tumor infiltrating lymphocytes (TIL) represents an attractive treatment option for patients with a variety of solid tumors. The basis for this therapy stems from the fundamental observation that tumor reactive lymphocytes are often found infiltrating the tumor microenvironment (TME). Adoptive cell therapy (ACT) utilizing TIL aims to exploit these naturally occurring immune responses by isolating these TILs from surgically resected tumors, expanding and activating the cells to large numbers ex vivo, and finally re-infusion of the product back into the host.

Interested physicians can contact Dr. Udai Kammula (PI; kammulaus@upmc.edu) or Ms. Krystle Eaton (Program Supervisor , mientkiewiczk@upmc.edu) with inquiries.

TLR9 AGONIST IN COMBINATION WITH IMMUNOTHERAPY FOR TREATMENT OF MELANOMA

Neoadjuvant Phase II Study of TLR9 Agonist CMP-001 in Combination with Nivolumab in Stage IIIB/C/D Melanoma Patients with Clinically Apparent Lymph Node/In-Transit Disease

HCC# 17-169

The primary objective of this study is to evaluate pathologic response rate (PRR) in patients with stage IIIB/C melanoma following 7 weeks of nivolumab and injected CMP-001.

CMP-001 is a type A toll-like receptor 9 (TLR9) agonist comprising unmethylated CpG motif-rich G10 oligonucleotides encapsulated in noninfectious virus-like particles (VLPs). CMP-001 has single-agent anti-cancer activity. In this study, CMP -001 is administered intra-tumorally along with intravenous nivolumab for 7 weeks prior to planned surgical resection. Subcutaneous CMP-001 and nivolumab are continued after surgery to complete 1 year of therapy.

Early results are promising. Interested physicians can contact Dr. Diwakar Davar (PI; davard@upmc.edu) or Ms. Amy Rose (Melanoma Program Manager, kennaj@upmc.edu) with inquiries.

High Priority Trials in the Community

HER2 Negative Breast Cancer

17-185: A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer

PI: Dr. Adam Brufsky, brufskyam@upmc.edu

17-053: A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial

PI: Dr. Gijsberta Van Londen, vanlondenj@upmc.edu

Triple Negative Breast Cancer

17-016: A Randomized Phase III Trial to Evaluate the 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 Neo-adjuvant Chemotherapy

PI: Rachel Jankowitz, jankowitzr@upmc.edu (Adam Brufsky, brufskyam@upmc.edu)

Non-Small Cell Lung Cancer

16-153: A phase II clinical trial evaluating the efficacy of atezolizumab in advanced non-small cell lung cancer (NSCLC) patients previously treated with PD-1-directed therapy

PI: Dr. Liza Villaruz, Villaruzl@upmc.edu

Prostate Cancer

18-023: Cabazitaxel with Abiraterone versus Abiraterone alone Randomized Trial for Extensive Disease following Docetaxel: the CHAARTED2 Trial

PI: Dr. Leonard Appleman, applemanlj@upmc.edu

Physicians should contact the study's PI or Donna Haney (Community Network Program Manager, haneydl@upmc.edu) with inquiries.

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Clinical Research Services (CRS) is made up of over 100 staff members who facilitate development, implementation, coordination, internal data monitoring, and completion of approximately 250 oncology-focused trials at Hillman each year. These trials include institutional (investigator-initiated), multi-center cooperative group/National Clinical Trial Network (NCTN), consortium, and industry-sponsored trials. Using a disease-specific centers model for conducting clinical trials, CRS provides study development and implementation assistance, submissions to the FDA, IRB processing, patient recruitment, study coordination, study-specific training, data collection, and specimen collection and processing.