THE **TRIAL** BLAZER

UPMC HILLMAN CANCER CENTER

A quarterly newsletter from CLINICAL RESEARCH SERVICES

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INTRODUCTION

Dear Colleagues,

We would like to welcome you to the second edition of the UPMC Hillman Cancer CRS newsletter and start by extending a hearty congratulations to the physicians and entire CRS team on the fantastic start in the efforts to meet and potentially surpass our 2019 trial accrual goals. We have accrued 234 patients in therapeutic trials during the first quarter of 2019, an increase of 13% from the first quarter of 2018. We deeply appreciate your contributions so far and continue to solicit your support in achieving our laudable goal. The support has also been practically reflected in the number of extremely riveting and innovative entries we received in the newsletter naming competition. They truly reflected the visionary character of our team. *The Trial Blazer* emerged as the staff favorite and winner. We do believe this title is befitting as you all continue to pave the way for new, exciting, and innovative trials designed to improve cancer treatments and diagnosis for all patients. As always, we encourage any comments and suggestions on the newsletter. For this effort to have an impact, your feedback, whether negative or positive are highly coveted. We would also like ideas on what you would like to see included in this publication. We need all hands on deck to make this a success.

Thank you for your hard work,

Antoinette (Toni) Wozniak, MD, FACP, FASCO
Associate Director of Clinical Research

Bhanu P. Pappu, PhD, MHA
Vice President of Clinical Operations and Strategy

NEW UNIVERSAL CONSENT FOR GENOMIC SEQUENCING FOR UPMC HILLMAN CANCER CENTER

Do you order genomic testing through Foundation Medicine, TEMPUS, CARIS, or internally through Pathology or the UPMC Genome Center?

As part of our NCI mandate, we have started a new initiative to enroll every patient undergoing SOC/research genomic testing under the new HCC 18-177 protocol that allows our investigators to follow these patients for clinical progression, treatment decisions, and outcomes analysis.

You also have the option to obtain biological specimens for other biomarker analyses. By integrating various data analytics platforms across the cancer center, our goal is to make this new resource available to all Hillman investigators to advance our clinical and research mission.

Please contact any CRS coordinator to enroll your oncology patients who have already had or are going to get genomic testing (retrospective and prospective). The 18-177 protocol is available through this link: 18-177.

This is a joint effort of all HCC investigators, under my direction, in preparation for the CCSG core grant renewal, to guide and improve oncology treatment practices and contribute to advancing preclinical and clinical cancer research at UPMC and the University of Pittsburgh.

Please use 18-177 for all genomic analyses.

Sincerely,

Robert L. Ferris, MD, PhD
Director

POINTS OF INTEREST

Accrual Statistics for 2019

- Open to Accrual Studies
- Non-therapeutic (Interventional) Referrals
- Therapeutic Referrals

Spotlight Trials

- TIL Therapy for Biliary Tract Cancer
- TIL for Novel Cancer Types
- Fecal Microbiome Transplantation in PD-1 Refractory 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

WINNER OF NEWSLETTER NAMING COMPETITION

Congratulations to Amy Dameron, senior safety specialist at CRS, the winner of the newsletter naming competition, and to all of us for continuing to work together as a winning team.

2019 OPEN STUDIES

Disease Center	Current OTA Trials	Interventional Accruals	Therapeutic Accruals
Breast Center	34	28	27
GI/Esophageal Cancer Center	18	24	24
Melanoma Center	22	24	24
Prostate and Urologic Cancers	19	22	22
Hematological Malignancies Center	26	21	21
Head and Neck Center	13	20	20
Phase I (Experimental Therapeutics) Center	23	14	14
Gynecological Oncology Center	14	13	13
Brain Tumor Center	15	12	12
Lung and Thoracic Malignancies Center	26	21	11
Sarcoma Center	8	7	7
Pediatric Oncology	48	5	5
Biobehavioral Medicine in Oncology Program (BMOP)	11	76	0
Total		**287**	**200**
*Radiation Oncology Center	18	15	15
*Phase II Center	46	10	10

All accruals have been calculated for the first quarter of 2019 (Jan - Mar).
*Accruals counted within Disease Center of care.

2019 Q1 NON-THERAPEUTIC (INTERVENTIONAL) REFERRALS

Referring Physician	Number of Referrals
Amer Zureikat, MD	27
David Bartlett, MD	22
Seungwon (Steve) Kim, MD	17
Alex Olawaiye, MD	14
Brian Orr, MD	13
Jessica Berger, MD	11
John Waas, MD	11
Alexis Megaludis, MD	10
David Wilson, MD	10
Umamaheswar Duvvuri, MD	7
Matthew Holtzman, MD	7
Franklin Viverette, MD	7
Paniti Sukumvanich, MD	6
Afaq Ahmad, MD	5
Michelle Boisen, MD	5
Vincent Reyes, MD	5

2019 Q1 THERAPEUTIC REFERRALS

Referring Physician	Number of Referrals
John Rhee, MD	10
James Ohr, MD	8
John Kirkwood, MD	6
Diwakar Davar, MD	4
Umamaheswar Duvvuri, MD	4
Jing-Zhou Hou, MD	4
Yana Najjar, MD	4
Nathan Bahary, MD	3
Jessica Berger, MD	3
David Friedland, MD	3
Gaurav Goel, MD	3
Christopher Marsh, MD	3
Priscilla Mcauliffe, MD	3
Rita Mukhtar, MD	3
Shannon Puhalla, MD	3
Anastasios Raptis, MD	3
Vincent Reyes, MD	3
Robert Vanderweele, MD	3
Dan Zandberg, MD	3

SPOTLIGHT TRIALS

IIT – TIL THERAPY FOR BILIARY TRACT CANCER

18-126: A Phase 2 Study to Evaluate the Efficacy and Safety of Adoptive Transfer of Autologous Tumor Infiltrating Lymphocytes in Patients with Locally Advanced, Recurrent, or Metastatic Biliary Tract Cancers

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 locally advanced, recurrent, or metastatic biliary tract cancer using the objective response rate (ORR). The main secondary objective is to further evaluate the efficacy of this therapy using complete response (CR) rate, duration of response (DOR), disease control rate (DCR), progression-free survival (PFS), and overall survival (OS).

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

IIT – TIL FOR NOVEL CANCER TYPES

HCC# 19-004: A Phase 2 Study to Evaluate the Efficacy and Safety of Adoptive Transfer of Autologous Tumor Infiltrating Lymphocytes in Patients with Advanced Solid Cancers

This study has the primary objective of evaluating the efficacy of a non-myeloablative lymphodepleting preparative regimen followed by infusion of autologous TIL and high-dose aldesleukin in patients with one of the following types of locally advanced, recurrent, or metastatic cancers: 1.) gastric/esophagogastric, 2.) colorectal, 3.) pancreatic, 4.) sarcoma, 5.) mesothelioma, 6.) neuroendocrine, 7.) squamous cell cancer, 8.) Merkle cell, 9.) mismatch repair deficient and/or microsatellite unstable cancers, and 10.) patients who have exhausted conventional systemic therapy options by using the objective response rate (ORR).

The main secondary objectives are is to: a.) further evaluate the efficacy of this therapy using complete response (CR) rate, duration of response (DOR), disease control rate (DCR), progression-free survival (PFS), and overall survival (OS); and b.) characterize the safety profile of this therapy in patients with locally advanced, recurrent, or metastatic cancers in the following cohorts: 1.) gastric/esophagogastric, 2.) colorectal, 3.) pancreatic, 4.) sarcoma, 5.) mesothelioma, 6.) neuroendocrine, 7.) squamous cell cancer, 8.) Merkle cell, 9.) mismatch repair deficient and/or microsatellite unstable cancers, and 10.) patients who have exhausted conventional systemic therapy options.

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

IIT – FECAL MICROBIOME TRANSPLANTATION IN PD-1 REFRACTORY MELANOMA

17-034: Phase II Feasibility Study of Fecal Microbiota Transplant (FMT) in Advanced Melanoma Patients Not Responding to PD-1 Blockade

This study has the primary objective of investigating whether combining single PD-1 responder-derived FMT with pembrolizumab converts PD-1 non-responders to responders. The secondary objective is to investigate how FMT administration affects composition and function of T-cells and innate/adaptive immune system subsets. Intestinal dysbiosis has been linked to non-responsiveness to PD-1 checkpoint inhibition. In this study, we are administering PD-1 responder-derived fecal microbiome transplants to carefully selected PD-1 refractory patients.

Interested physicians can contact Dr. Diwakar Davar (PI, davard@upmc.edu) or Amy Rose (Melanoma Project Manager, kennaj@upmc.edu) with inquiries.

BEAT AML MASTER TRIAL USING PERSONALIZED MEDICINE APPROACH

The Leukemia & Lymphoma Society (LLS) is leading the Beat AML® Master Trial, a groundbreaking collaborative clinical trial testing several novel targeted therapies for patients with acute myeloid leukemia (AML). The primary objective of the study is

to improve AML therapy in a stepped, but expeditious manner with implementation of new technology and therapeutic approaches in a setting where conventional clinical trials have largely failed. By performing real-time molecular screening of newly-diagnosed AML patients in a multicenter clinical trial with treatment assignment based upon this determination, we will assess the efficacy of the best new AML therapies in defined subsets of patients who are most likely to benefit from novel, mechanism-based therapies.

The goal is to offer specific, targeted therapies to defined AML patient subsets (examples: FLT3 ITD positive, IDH1/IDH2 mutated, RAS mutated, complex karyotype/p53 mutated, surface antigen+) including "novel-novel" combination studies. For "marker-negative" patients who do not have a genomic or biologic correlate that allows for assignment to a specific targeted therapy, we will offer therapy with a novel AML agent with broad activity against the microenvironment or immune system. The trial will begin with four to five arms but will expand up to 10 arms including mechanism-based combinations for which dosing and scheduling has been established.

The trial is still open to accrual and interested physicians can contact an LLS information specialist to learn more.

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 Neoadjuvant 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.

Clinical Research Services (CRS) is made up of over 185 staff members who facilitate development, implementation, coordination, internal data monitoring, and completion of approximately 341 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.

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