AWARD NUMBER: W81XWH-20-1-0706

TITLE: Heating Cold Prostate Tumors with PSMA-Targeted Alpha Therapy and Pembrolizumab

PRINCIPAL INVESTIGATOR: Dr. Scott Tagawa, MD, MS

CONTRACTING ORGANIZATION: Joan & Sanford I.Weill Medical College of Cornell University, New York, NY

REPORT DATE: October 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2023	Annual	30Sep2022-29Sep2023

4. TITLE AND SUBTITLE

Heating Cold Prostate Tumors with PSMA-Targeted Alpha Therapy and Pembrolizumab

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-20-1-0706

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Scott Tagawa M.D

E-Mail: stt2007@med.cornell.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Joan & Sanford I. Weill Medical College of Cornell University
1300 York Avenue, Box 89
New York, NY 10065

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Treatment of prostate cancer using immune checkpoint inhibition combined with androgen receptor signaling inhibitors results is ineffective in most. Other methods of treatment need to be studied to develop novel strategies to improve prognosis of these patients. We hypothesize that the combination of pembrolizumab plus androgen receptor signaling inhibitor plus 225Ac-J591 is safe. We also hypothesize that the addition of 225Ac-J591 to the backbone of pembrolizumab plus androgen receptor signaling inhibitor will lead to more responses compare to pembrolizumab plus androgen receptor signaling inhibitor alone and that we can identify subsets more or less likely to respond. In this project, we will utilize our prospective data and sample sets to: (i) compare the efficacy of the addition of PSMA-targeted alpha emitting radionuclide therapy to anti-PD-1 and AR signaling inhibition versus pembrolizumab and AR signaling inhibition alone; and (ii) assess the optimal patient/tumor population for immune checkpoint inhibition with pembrolizumab with or without PSMA-targeted alpha emitting radionuclide therapy. This project will evaluate whether the combination of PSMA-based targeted radionuclide therapy using alpha emitting 225Ac with immune checkpoint inhibitor and androgen receptor signaling inhibitor will result in more accurate cancer cell targeting and more robust, systemic immune response to maximize their effects. The findings from this project may provide valuable information to help with uncovering cures for men with metastatic castration resistant prostate cancer.

15. SUBJECT TERMS
None listed.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	16	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

1. INTRODUCTION

BACKGROUND: Immunotherapy is of tremendous interest to both clinicians and patients based upon the possibility of deep, durable responses, but to date is of limited utility in men with advanced prostate cancer. Androgen receptor (AR) signaling inhibitors (ARSI) have significant efficacy for men with PC and interestingly, both pre-clinical and clinical data support the combination of AR signaling and immune checkpoint inhibition. PC is a radiosensitive disease, curing some men and providing palliation for others, including the bone-targeting isotope radium-223 with a survival benefit. There is both pre-clinical and clinical data supporting radiation to stimulate immune responses. Prostate-specific membrane antigen (PSMA) is a target of interest because of its high level of sensitivity and specificity for PC and PSMA-targeted radionuclides are headed towards approval. Of particular interest are PSMA-targeted alpha-emitters, with very high potency and the potential to generate immune response.

HYPOTHESES / OBJECTIVES: We hypothesize that (1) the addition of 225Ac-J591 will increase the durable response proportion to pembrolizumab plus AR signaling inhibitor and (2) that there are clinical and biomarker subsets associated with treatment outcome.

2. KEYWORDS

Prostate Cancer, metastatic castration resistant prostate cancer, PSMA, pembrolizumab, 225Ac-J591

3. ACCOMPLISHMENTS

What were the major goals of the project?

AIMS / STUDY DESIGN:

Aim 1: To compare the efficacy of the addition of PSMA-targeted alpha emitting radionuclide therapy to anti-PD-1 and AR signaling inhibition (versus pembrolizumab and AR signaling inhibition alone), we will perform a clinical trial in men with progressive mCRPC. First, an initial safety lead-in will assess the triplet combination of pembrolizumab, an AR signaling inhibitor of physician choice, and 2 different doses of 225Ac-J591 (one with minimal and one with moderate single-agent toxicity). Following determination of the optimal dose, a randomized phase II trial will treat subjects with a fixed dose of pembrolizumab 600 mg every 6 weeks (for up to 2 years) plus a standard AR signaling inhibitor (until progression or intolerance) with or without 225Ac-J591. The primary endpoint of the study will test the hypothesis that the addition of PSMA-targeted alpha emitter increases the response to immune-hormonal therapy with 90% power. Key secondary clinical endpoints include 1-year progression-free survival, duration of response, and overall survival.

Aim 2: To prospectively assess the optimal patient/tumor population for immune checkpoint inhibition with pembrolizumab with or without PSMA-targeted alpha emitting radionuclide therapy, we will evaluate immune response, genomic biomarkers, and PSMA molecular imaging and will also evaluate patient reported outcomes.

What was accomplished under these goals?

Specific Aim 1:
Major Task 1: Obtain regulatory approval for multicenter study.

Subtask 1: We have completed all parts of Subtask 1 during the initial portion of the funding period. The initial protocol was reviewed, amended following discussions with our pharmaceutical partner (Merck), and subsequently approved. The amended version of the protocol was approved by the Genitourinary Disease Management Team, the Meyer Cancer Center Protocol Review and Monitoring Committee, Radiation Safety Committee, and WCM IRB. Following local approval, approval by HRPO and FDA occurred. The protocol has been activated at WCM and BMH (i.e. both milestones have been achieved).
The study start-up process is ongoing at CUMC and is in negotiations with DFCI. Furthermore, at least 2 other sites have expressed interest in participating. The process to onboard these sub-sites is ongoing. This study has been added to the PCCTC consortium (LOI #: c23-336).

Major Task 2: Coordinate and train study personnel for clinical trials
Subtask 1: WCM personnel have been fully trained with ongoing training for amendments. A site initiation visit was conducted for BMH personnel and training records have been accordingly amended.
Regulatory start-up is on-going for this study at CUMC. Once approved, formal training will occur.

Major Task 3: Conduct clinical trial
Subtask 1: Enrollment and analysis of the phase I portion of the study has been completed. Enrollment in the randomized portion of the trial has been activated in August, 2022.

Table for Phase I patient enrollment:

Phase 1 Enrollment to Trial to Date		**12**	
Patients by Age			
20-29	0	30-39	0
40-49	0	50-59	3
60-69	4	70-79	0
80-89	5	90+	0
Total: 12			
Patients by Gender			
Male	12	Female	0
Total: 12			
Patients by Race			
White	11	African American	1
Asian	0	Native Hawaiian or Other Pacific Islander	0

American Indian or Alaska Native	0	Unknown	
Total: 12			
Patients by Ethnicity			
Hispanic	1	Non-Hispanic	11
Unknown			
Patients Who Completed the Study		**4**	
Patients Who Have Dropped Out of the Study		**2**	

Table for Phase II Randomized:

Enrollment to Trial to Date		**10**	
Patients by Age			
20-29	0	30-39	0
40-49	0	50-59	
60-69	2	70-79	5
80-89	3	90+	0
Total: 10			
Patients by Gender			
Male	10	Female	0
Total: 10			
Patients by Race			
White	7	African American	2
Asian	0	Native Hawaiian or Other Pacific Islander	0
American Indian or Alaska Native	0	Unknown	1
Total: 16			
Patients by Ethnicity			
Hispanic		Non-Hispanic	9
Unknown	1		
Patients Who Completed the Study		**0**	
Patients Who Have Dropped Out of the Study		**0**	

Subtask 2:
Preliminary information regarding the phase I portion of the study was presented at the 2022 Society of Urologic Oncology annual meeting in December, 2022. The final phase I safety and preliminary efficacy results were then published in an abstract and presented at the 2023 ASCO Genitourinary Cancers Symposium.

In this phase of the study, we had hypothesized that the addition of a potent alpha-PSMA-TRT (^{225}Ac-J591) will lead to double-stranded DNA breaks, cell death, and subsequent generation/release of neoantigens, thereby increasing the response proportion and duration to pembrolizumab plus ARSI. The primary endpoint for the phase I portion of the study was the determination of ^{225}Ac-J591 dose for the randomized phase II portion.

6 patients were enrolled and treated in each dose-level (65 KBq/kg and 80 KBq/kg) cohort. All 12 patients experienced PSA decline following therapy with 6 patients with >50% decline, as illustrated in the Figure 1 below, for both those who received ^{255}Ac-J591 at 65 KBq/kg (blue) and 80 KBq/kg (orange). Interestingly, with > 9 months follow-up, 4 patients (33% of all patients; all at 80 KBq/kg) remained progression-free and on study.

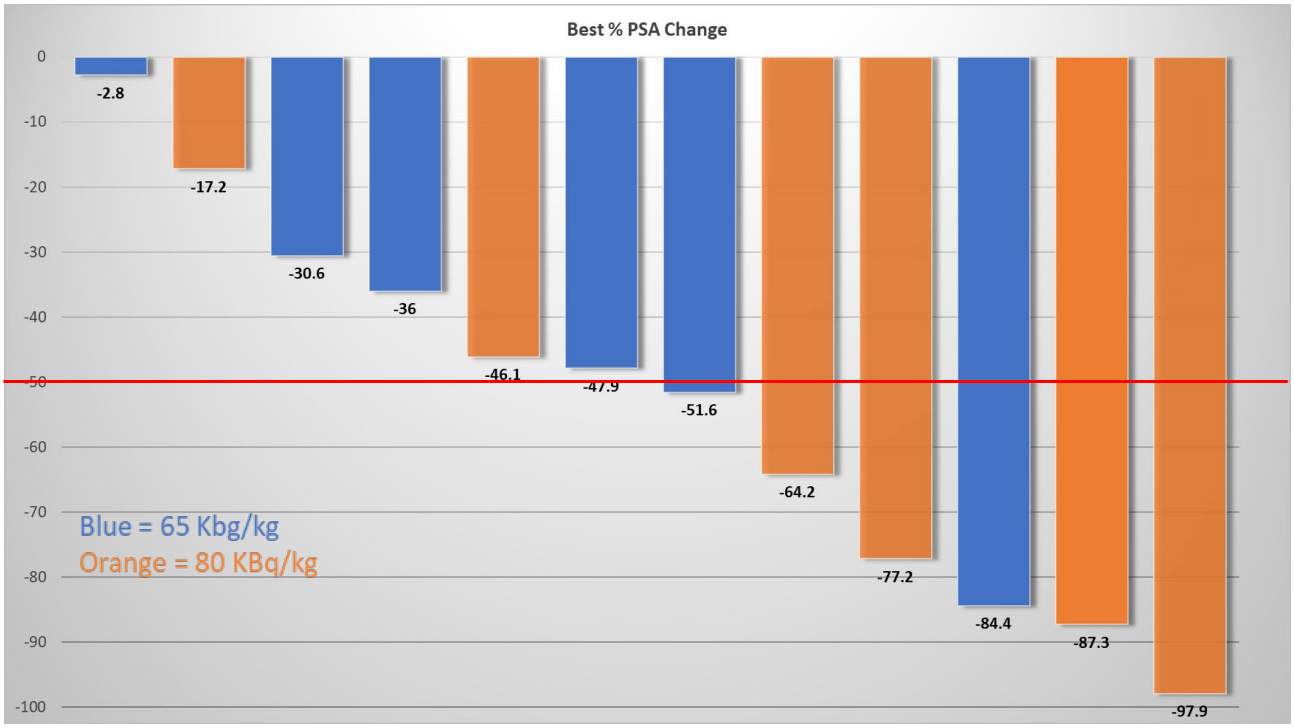

Figure 1: Waterfall diagram depicting PSA responses by dose of 225Ac-J591.

There were 7 patients that developed an unexpected syndrome hypothesized to be related to cytokine release around 10 days following C1D1 treatment that was characterized by morbilliform rash, fever > 101F and decreased blood counts. In addition, several of the following inflammatory markers were elevated: IL, D-Dimer, ferritin, fibrinogen, and ESR. After pausing the ARSI, this reaction improved within 1 week. These patients had both earlier and greater platelet/neutrophil decline compared to patients who did not exhibit this syndrome, along with rapid count recovery (Figure 2).

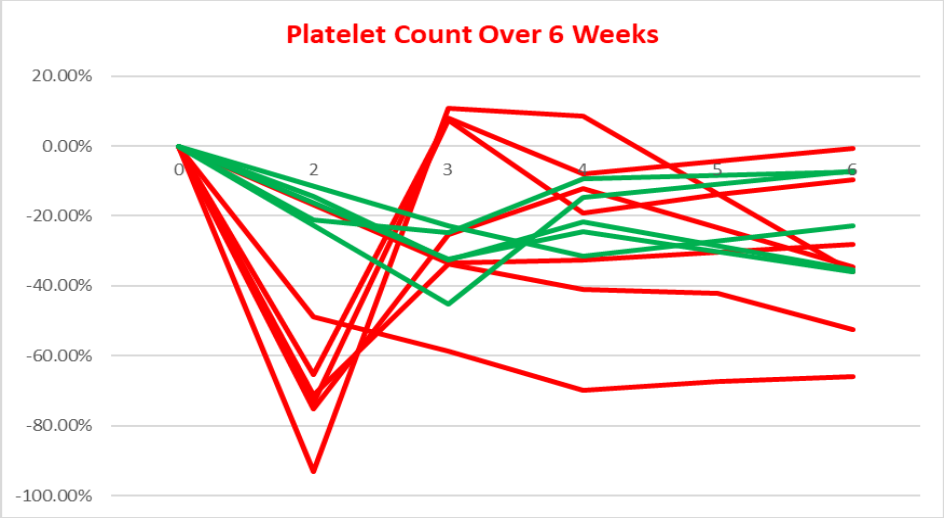

Figure 2: Spider plot depicting percent change in platelet count over first 6 weeks on study for patients with (red) and without (green) the syndrome of rash and fever.

Overall, combination therapy with alpha-PSMA-TRT, ARSI, and pembrolizumab demonstrated feasibility in phase I. Furthermore, ^{225}Ac-J591 at 80 KBq/kg was selected as the phase II dose, as there was no significant difference in adverse events between the two dose levels, but potentially better efficacy. The randomized Phase II portion of the trial is ongoing.

Specific Aim 2:
Major Task 4: (Aim 2a) Evaluation of immune response
Subtask 1:
Collection and processing/storage of serum samples is ongoing.

Subtask 2:
Collection and processing/storage of markers of immunogenic cell death is ongoing.

Subtask 3:
Collection and processing/storage of samples for microbiome is ongoing.

Major Task 5: (Aim 2b) Genomic biomarkers
Subtask 1:
Collection of tissue samples is ongoing.

Subtask 2:
Collection and processing/storage of plasma is ongoing.

Major Task 6: (Aim 2c) Molecular imaging
Baseline and post-treatment PET imaging is ongoing.
Preliminary analysis of pre-treatment PET imaging for the phase I portion of the study was submitted in abstract form to the 2023 ASCO Genitourinary Cancers Symposium.

Major Task 7: (Aim 2d) Patient reported outcomes
Collection of FACT-P, FACT-RNT, BPI, and EQ-5D-5L questionnaires is ongoing.

What opportunities for training and professional development has the project provided?

A medical oncology fellow (Michael Sun) participated in the analysis of the phase I portion of the protocol and presented initial results at the 2022 SUO meeting. This fellow has also published and presented updated phase I results at the 2023 ASCO GU Cancers Symposium. Related to his work with ^{225}Ac-J591, he received funding via an ASCO Young Investigator Award.

How were the results disseminated to communities of interest?

The preliminary introduction and results of the phase I portion of the study were submitted in abstract form and presented at the 2022 SUO meeting. Updated final phase I safety results including an inflammatory syndrome that appears to be cytokine-driven were published in abstract form and presented at the 2023 ASCO GU Symposium.

What do you plan to do during the next reporting period to accomplish the goals?

The study is co-funded by Weill Cornell Medicine and Merck in addition to DoD funds. As stated in the proposal and SOW, we will continue accrual at the WCM and BMH sites. We will proceed with study start up at additional sites within the PCCTC and anticipate accrual before the next annual report.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change
Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

The demand for actinium-225 has increased at a higher rate than supply has increased. This is potentially an issue as a vital material for labeling of the study drug. We have anticipated this and now have a standing order with the Department of Energy that is projected to more than cover needs for this study.

The issue with delayed reports has improved since the last annual and semi-annual reporting period, with the additional GU Clinical Trials Administrator on the team, however there is still progress to be made to submit all reports prior to the deadline.

Changes that had a significant impact on expenditures

There is an ongoing workforce shortage within the clinical research enterprise at our institution and at other institutions involved in this protocol. This has resulted in some delays in study start up. This has not resulted in any significant impact on expenditures to date, but the duration of the overall study may necessitate a no cost extension.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents:

Nothing to report.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents
N/A

6. PRODUCTS

- **Publications, conference papers, and presentations**

  Journal publications.

  Nothing to report.

  Books or other non-periodical, one-time publications.

  Nothing to report.

Other publications, conference papers and presentations.

Abstract/Poster from December 2022:
https://suo-abstracts.secure-platform.com/a/gallery/rounds/15/details/2687

Abstract/Poster from February 2023:
https://ascopubs.org/doi/abs/10.1200/JCO.2023.41.6_suppl.181

Michael Philip Sun, Jones T. Nauseef, Jessica Palmer, Joseph Earl Thomas, Judith Stangl-Kremser, Mahelia Bissassar, Sandra Huicochea Castellanos, Joseph Osborne, Ana M. Molina, Cora N. Sternberg, David M. Nanus, Neil Harrison Bander, and Scott T. Tagawa. Phase I results of a phase I/II study of pembrolizumab and AR signaling inhibitor (ARSI) with 225Ac-J591. Journal of Clinical Oncology 2023 41:6_suppl, 181-181.

- **Website(s) or other Internet site(s)**

  Nothing to report.

- **Technologies or techniques**

  Nothing to report.

- **Inventions, patent applications, and/or licenses**

  Nothing to report.

- **Other Products**

  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Personnel	Role	Person Month Effort	Percent Effort
Scott Tagawa	PD/PI	0.90 CM	7.54%
Karla Ballman	Co-Investigator	0.26 CM	2.2%
Paul Christos	Co-Investigator	0.12 CM	1%
Neil Bander	Co-Investigator	0.27 CM	2.26%
Paraskevi Giannakakou	Co-Investigator	0.60 CM	5%
Francesca Khani	Co-Investigator	0.00 CM	0%
Joseph Osborne	Co-Investigator	0.00 CM	0%

Mahelia Bissassar	Program Specialist	0.19 CM	1.59%
Charlene Thomas	Staff Statistician	4.04 CM	33.71%
Angela Tan	Research Nurse	1.28 CM	10.67%
Catrina Estrella	Technician	4.06 CM	33.86%

Name: Scott Tagawa, M.D
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.9
Contribution to Project: Dr. Tagawa oversees the entire program, including organizing bi-weekly meetings, reviewing enrollment, meeting with WCM data coordinators and administrative staff, developing new protocols, and enrolling patients on studies. He identifies and recruit patients to the protocol and oversees all conduct of the study.

Name: Paraskevi Giannakakou, M.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.6
Contribution to Project: Dr. Giannakakou assists Dr. Tagawa in coordinating and supervising all translational and correlative sciences for all studies.

Name: Neil Bander, MD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.27
Contribution to Project: Dr. Bander assists Dr. Tagawa in coordinating and supervising bi-weekly meetings, review eligible patients, meeting with relevant staff associated with the projects and developing new protocols.

Name: Karla Ballman, PhD
Project Role: Collaborator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.26
Contribution to Project: Dr. Ballman assists with biostatistical design of WCM investigator initiated studies.

Name: Paul Christos, DrPH
Project Role: Collaborator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.12
Contribution to Project: Dr. Christos assists with biostatistical design of WCM investigator initiated studies.

Name: Francesca Khani, M.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.0
Contribution to Project: Dr. Khani assists Dr. Tagawa in coordinating and supervising all translational sciences for all studies.

Name: Joseph Osborne, M.D.

Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.0
Contribution to Project: Dr. Osborne assists in the administration the investigational products for this clinical protocol.

Name: Mahelia Bissassar
Project Role: Program Specialist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.19
Contribution to Project: Ms. Bissassar reports directly to Dr. Tagawa. She guides clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites.

Name: Charlene Thomas
Project Role: Statistician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4.04
Contribution to Project: Ms. Thomas assists with biostatistical design of WCM investigator initiated studies.

Name: Angela Tan
Project Role: Research Nurse
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.28
Contribution to Project: Ms. Tan assists with recruitment of patients, completion of study procedures, assessment of adverse events

Name: Catrina Estrella
Project Role: Technician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4.06
Contribution to Project: Ms. Estrella assists with processing of samples in Dr. Giannakakou's lab.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Scott Tagawa

*Title: Measuring Patient-Reported Outcomes Related to Radiopharmaceuticals for Prostate Cancer

Major Goals: Goal is to create a new patient-reported outcomes measure for patients receiving targeted radionuclide therapy

*Status of Support: Active (New)

Project Number: W81XWH-20-1-0351

Name of PD/PI: Gonzalez, Brian

*Source of Support: DoD

*Primary Place of Performance: Weill Cornell Medicine, NY, NY

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/01/2020-08/31/2023

* Total Award Amount (including Indirect Costs):

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2022	0.36
3. 2023	0.36

Title: Targeted Therapies
Major Goals: 1) Optimize PSMA-targeted therapeutics (including radionuclides, bispecifics, and drugs) 2) Advance PC immunotherapeutics based on pre-clinical investigations 3) Develop new therapies for neuroendocrine / small cell PC 4) Identify effective treatments and biomarkers based on discovery of mechanisms of PC therapy resistance and sensitivity 5) Open PCCTC studies to underrepresented minorities in Brooklyn and Upper Manhattan (incl. VAMC)

*Status of Support: Active (New)

Project Number: W81XWH-22-2-0018

Name of PD/PI: Tagawa, Scott

*Source of Support: Department of Defense

*Primary Place of Performance: Weill Cornell Medicine, NY, NY

Project/Proposal Start and End Date: (MM/YYYY) (if available): 9/30/22 – 9/29/26

* Total Award Amount (including Indirect Costs):

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	1.8
2. 2024	1.8
3. 2025	1.8
4. 2026	1.8

Title: Clonal Hematopoiesis as a Determinant for Bone Marrow Toxicities for Targeted Radiation Therapies in Prostate Cancer
Major Goals: Goal is to identify clonal hematopoiesis mutation signatures that predict short term and long-term bone marrow toxicities from targeted radiation therapies (TRT) in prostate cancer

Status of Support: Active (New)

Project Number: W81XWH-22-1-0375

Name of PD/PI: Desai, Pinkal

Source of Support: DoD

Contracting/Grants Officer: Joshua D. McKean

Primary Place of Performance: Weill Cornell Medical College, New York

Project/Proposal Start and End Date: (MM/YYYY) (if available): 9/30/22-9/29/25

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	1.2 calendar
2. 2024	1.2 calendar
3. 2025	1.2 calendar

Ended

R01CA207645 (Osborne)
A new technique to make 68GA-labeled pharmaceuticals widely available for clinical use.
NIH/NCI
Effort: 0.36 calendar
Grants Officer: George Redmond, redmondg@mail.nih.gov
07/22/2016-06/30/2020
Project Goals/Aims: This proposal aims to establish a new technology for the production and distribution of a prostate cancer imaging agent based on the short-lived radioisotope Gallium-68. The new technology allows for the production of about 100 times larger quantities of Gallium-68 than existing techniques.
Role: Co-Investigator

W81XWH-18-1-0527 (Tagawa/ Beltran/ Bander)*
Molecular and clinical correlates with prostate-specific membrane antigen (PSMA)-targeted radionuclide therapy
Department of Defense
Effort: 1.20 calendar
Grants Officer: Janet P. Kuhns, janet.p.kuhns.civ@mail.mil
09/30/2018-09/29/2024 (NCE with only remaining funds on Beltran portion of grant)
Project Goals/Aims: The goal of this project is to determine the best genomic, clinical, and imaging characteristics for successful PSMA-TRT and described immune response from PSMA-TRT. Specific Aims: 1. Prospectively and retrospectively assess genomic biomarkers and gene expression changes associated with outcome from anti-PSMA targeted radionuclide therapy. 2. Prospectively and retrospectively assess clinical parameters associated with outcome from anti-PSMA- TRT. 3. Prospectively and retrospectively assess PSMA expression as determined by PSMA molecular imaging associated with response to anti-PSMA -TRT. 4. Evaluate generation of an immune response following anti-PSMA-TRT in association with clinical outcome.
Role: Principal Investigator

2014 Movember -PCF GTSC Award (Armstrong/Nanus)
Development of Circulating Molecular Predictors of Chemotherapy and Novel Hormonal Therapy Benefit in Men with Metastatic Castration Resistant Prostate Cancer (mCRPC)
Supporting Agency: Prostate Cancer Foundation
Effort: 0.60 calendar
Grants Officer: Howard R. Soule, Prostate Cancer Foundation; email: hsoule@pcf.org
08/01/2014 – 7/31/2019 (NCE)
Project Goals/Aims: This project aims 1. Assessment of a CRPC molecular taxonomy based on circulating tumor cell (CTC) molecular profiles in men prior to abiraterone acetate (AA) or enzalutamide therapy and, 2. To describe treatment-emergent CRPC genotypes during AA, enzalutamide, and taxane-based therapy using longitudinal CTC and circulating biomarkers.

Role: Co-Investigator

W81XWH-09-1-0596 (Tagawa)
Title: A Randomized Phase 2 Trial of 177Lu Radiolabeled Anti-PSMA Monoclonal Antibody J591 in Patients with High-Risk Castrate Biochemically Relapsed Prostate Cancer
Supporting Agency: Department of Defense
Effort: 1.20 calendar
Grants Officer: Janet P. Kuhns; janet.p.kuhns.civ@mail.mil
Performance Period: 8/17/2009-08/16/2020 (NCE)
Project Goals/Aims: To demonstrate a difference in the proportion of men with radiographically evident metastatic disease at 18 months in those receiving anti-PSMA-based RIT vs placebo.
Role: Principal Investigator

What other organizations were involved as partners?

Columbia University Medical Center

8. SPECIAL REPORTING REQUIREMENTS

N/A

9. APPENDICES

N/A