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TITLE: Combination Immunotherapy for the Treatment of High-Risk HER2-Positive Breast Cancer

PRINCIPAL INVESTIGATOR: Isabelle Bedrosian, MD

CONTRACTING ORGANIZATION: The University of Texas MD Anderson Cancer Center
Houston, TX

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The University of Texas MD Anderson Cancer Center
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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The goal of the proposed research is to complete a clinical trial that evaluates the ability of the combination of trastuzumab and the HER2-derived vaccine NeuVax™ (nelipepimut-S administered with the immunoadjuvant, GM-CSF) in the adjuvant setting to prevent metastatic disease in high-risk HER2-positive breast cancer patients. We hypothesize that combination therapy with trastuzumab plus vaccination is a therapeutic modality that has minimal toxicity and will prevent disease recurrence. Over the course of the funding period, we completed accrual to the trial outlined in Specific Aim 1. Primary vaccination series were completed for all randomized patients and booster inoculations were completed for all but 3 patients (as of 12/2020). An interim analysis has also been completed and overall the intervention was well tolerated. Across 2400 follow up visits, 16 instances (0.7%) of serious adverse events (AEs) were reported. The majority (75.8%) of the AEs were anticipated and the AEs were about equally divided between local and systemic toxicities. Dose reduction was required for 36 doses (1.5%) administered. Twelve recurrences and 1 death has been reported during the follow up period for an overall estimated 3 year DFS of 82%. Patients enrolled on the trial had the immune response assessed in vivo using a delayed type hypersensitivity (DTH) reaction and in vitro by assessing for the presence of E75-specific cytotoxic lymphocytes (CTL) in their peripheral blood. The DTH data has been acquired and is being analyzed; blood has been collected at all designated timepoints and dextramer assays are being performed to assess the E75-CTL response. Additional blood has been collected to establish a biobank for completion of future immune correlative studies (aim #3).
Blood samples for immunologic monitoring are being collected at the specified time points, processed, and stored for the planned analyses described in specific aims 2 and 3.

15. SUBJECT TERMS

Breast cancer, HER2- positive, immunotherapy, vaccines, NeuVax™, clinical trial

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. Introduction

Despite advances in treatment, it is estimated that approximately 20% of women diagnosed with invasive breast cancer will recur and may eventually succumb to their disease. One group at high risk for recurrence are patients with HER2-positive tumors who do not achieve a pathologic complete response (pCR) after receiving chemotherapy plus trastuzumab in the neoadjuvant setting. Novel therapeutic strategies are therefore needed for patients failing to achieve a pCR. Our group has been investigating HER2-derived peptide vaccines that elicit a HER2-specific cytotoxic T lymphocyte (CTL) response. Our primary *objective* during the funding period was to conduct a clinical trial to assess the ability of the combination of trastuzumab and the HER2-derived peptide vaccine nelipepimut-S+GM-CSF (NeuVax), given in the adjuvant setting, to prevent recurrences in patients with HER2-positive breast cancer who failed to achieve a pCR following receipt of HER2 targeted neoadjuvant chemotherapy. Our *central hypothesis* was that combination therapy with trastuzumab plus vaccination is a non-toxic therapeutic modality that would prevent disease recurrence in these patients thereby eliminating the mortality associated with HER2-positive metastatic breast cancer.

2. Keywords

Breast cancer
HER2-positive
Immunotherapy
Vaccine
NeuVax™
Clinical trial

3. Accomplishments

The focus of this research was to assess the ability of the combination of trastuzumab and the HER2-derived peptide vaccine, NeuVax, given in the adjuvant setting, to prevent disease recurrence in patients with HER2-positive breast cancer who were administered HER2 targeted neoadjuvant chemotherapy and did not achieve a pCR. To address this question, we conducted an investigator-initiated, multi-center, prospective, randomized, blinded, placebo-controlled phase II trial to test our *central hypothesis* that combination therapy with trastuzumab plus NeuVax™ (nelipepimut-S+GM-CSF) vaccination is a therapeutic modality with minimal toxicity that would prevent disease recurrence and reduce mortality from HER2-positive metastatic breast cancer.

Major goals

Specific Aim #1. Determine the efficacy of nelipepimut-S+GM-CSF administered with trastuzumab in the adjuvant setting in patients with HER2-positive breast cancer not achieving a pCR after neoadjuvant chemotherapy plus trastuzumab.

To address this aim, we completed a clinical trial entitled "Phase II trial of combination immunotherapy with nelipepimut-S + GM-CSF (NeuVax™) and trastuzumab in high-risk HER2+ breast cancer patients". This trial was conducted across 22 sites and successfully met its target of 100 eligible patients. As of December 2020, all but 3 participants have completed all protocol required interventions; the remaining 3 patients have completed the primary vaccination series but continue to receive booster immunizations.

Key administrative and regulatory steps addressed during the conduct of the trial include the following:

- The University of Texas MD Anderson Cancer Center (MD Anderson) Institutional Review Board (IRB) Approval (proposed date of completion was pre-award)
    - Initial IRB approval obtained on 18 Jun 2014
    - Following USAMRMC ORP HRPO review, IRB approval of revised protocol was obtained on 5 Nov 2014.

- USAMRMC ORP HRPO Approval (proposed date of completion was pre-award)
    - Protocol was submitted for review on 4 Aug 2014
    - USAMRMC ORP HRPO review identified several revisions that focused primarily on identification of an independent research monitor as well as inclusion of language to indicate that USAMRMC ORP HRPO should be notified in cases of serious adverse events, can perform site visits, and have access to study-related records. These revisions were made and the protocol was re-submitted to USAMRMC ORP HRPO on 20 Sep 2014.
    - Revisions were accepted after which the protocol was re-submitted to the MD Anderson IRB where it was approved on 5 Nov 2014. Notification of that approval was forwarded to the USAMRMC ORP HRPO which ultimately approved the protocol on 29 Dec 2014.

- Trial activation (proposed date of activation was 1 Oct 2014)
    - The trial was activated on 29 Jan 2015

- Trial amendments:
    - First amendment was approved by the MD Anderson IRB on 1 Dec 2015
        - Protocol changes include:
            - Broadened the window of time during which the vaccine could be administered after completion of trastuzumab infusion from 30-120 minutes to 15-120 minutes.
            - Added text to clarify the timing of when booster inoculations are administered.
            - Due to additional reports of the safety of peptide vaccines, the period of time during which patients are monitored following inoculation was changed from 60 minutes to 30 minutes with vital signs taken as clinically indicated.
            - Clarified the exclusion criteria related to autoimmune disease to reflect that patients with a history of autoimmune disease that are no longer requiring treatment are eligible. Specifically, changed test from “History of autoimmune disease” to “Any active autoimmune disease requiring treatment, with the exception of vitiligo.”
            - Modified the instructions regarding dosage and preparation to be consistent with the new mixing instructions and Investigator’s brochure for the vaccine provided by the manufacturer, Galena Biopharma.
            - Clarified how the injection site reaction is assessed depending on whether the patient returns to the study site or is contacted by phone by study staff 48-72 hours after inoculation.
            - Clarified that patients experiencing a serious adverse event (SAE) unrelated to study drug can be continued on the study if they desire to do so and it is determined safe for them to do so by the PI and the DoD study monitor.
    - Second amendment was approved by the MD Anderson IRB on 11 Jul 2016.
        - Protocol changes include:
            - Revised the eligibility criteria to include patients who are found to be HLA-A24 or HLA-A26 positive.
            - Clarified the timing of initiation of study intervention relative to standard of care treatments.
            - Clarified that standard of care pertuzumab is allowed.
            - Clarified that the area of inoculation will be at a location midway between the inguinal ligament and the knee preferably, but may be given in the arm.
            - Corrected referenced appendix for the NCI CTCAE version 4.03 from Appendix B to Appendix C.
            - In section 4.4.4 detailing blood collection and processing, clarified the immunologic assessments to be consistent with the study flowchart.

        - Added to the protocol a formal interim analysis for safety to be performed after the midpoint of enrollment and randomization.
    - Third amendment was approved by the MD Anderson IRB on 14 May 2017.
        - Protocol changes include:
            - Clarification that the vaccine could be administered 15-120 minutes after completion of trastuzumab infusion. Previously the protocol stated 30-120 minutes, but 15 minutes after PI approval.
            - Clarified that the period of observation after inoculation would be 30 min +/- 5 minutes. Previously stated 1 hour.
            - Clarified that the history and physical examination as well as height and weight assessment could be performed by an advance practice practitioner designated by the physician.
- The Study Chair of the protocol was changed from Dr. Elizabeth Mittendorf to Dr. Isabelle Bedrosian on November 13, 2017. This change was made when as Dr. Mittendorf has moved from MD Anderson to the Dana-Farber/Brigham and Women's Cancer Center

Trial accrual and interim analysis

Enrollment of patients with HER2-positive breast cancer began late January 2015 and the final patient randomized in October 2018 at which point the study was closed to further accrual. In total, 242 women signed HLA screening consent forms, 186 were confirmed to be HLA-A2/A3/A24/A26 status and 100 elected to move forward with randomization and treatment. All patients have received their primary vaccination series, 3 patients (as of December 2020) continue their protocol specified booster injections.

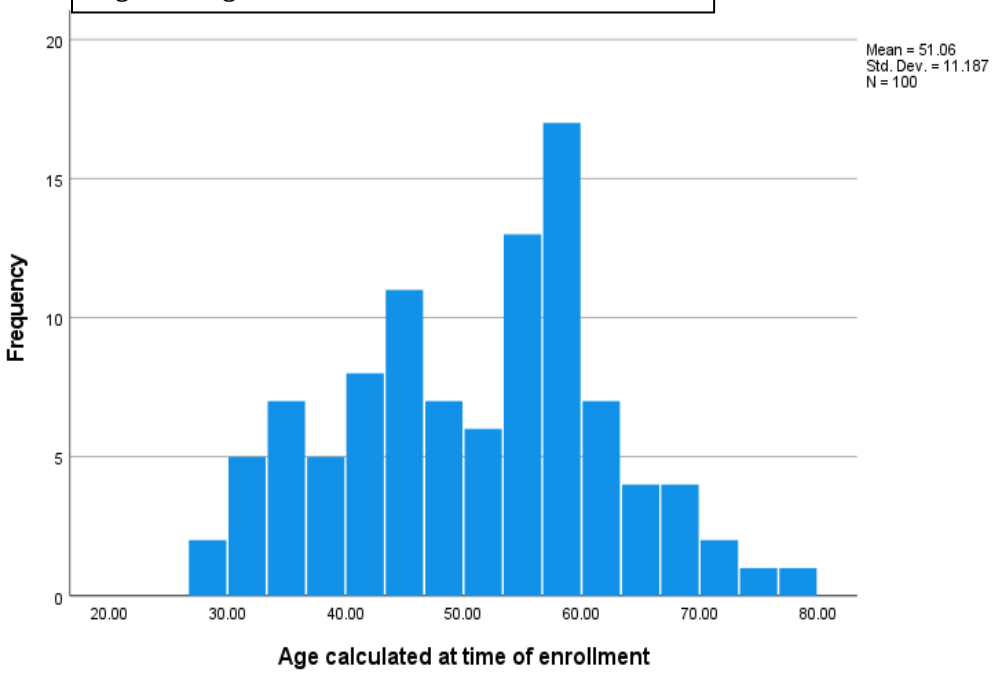
Patient demographics are outlined in Table 1 and demonstrate that minority populations accounted for over 1/3 of the accrual.

Table 1: Cohort demographics

	Number	Percent of total
Asian	6	6.0%
Black	10	10.0%
Hawaiian/Pacific Islander	1	1.0%
Hispanic	15	15.0%
Native American	1	1.0%
Other/Unknown	1	1.0%
White	62	62.0%
White,Hispanic	4	4.0%

Consistent with the prevalence of breast cancer, most women enrolled in the study were post-menopausal. Age distribution at time of enrollment is shown in Figure 1.

Figure 1: Age distribution at time of trial enrollment



Tumor characteristics are summarized in Table 2. As anticipated for HER2+ disease, invasive ductal cancer represented the primary histologic group. Most tumors were also ER and/or PR positive. Of the 11 women who did not have HER2 3+ reported by immunohistochemistry, 3 underwent FISH testing with HER2 copy number >6 and thus eligible to participate. The remaining 8 had FISH >4 but less than 6 and although the required DUAL-ISH confirmation was not completed, these women remained on study as per intent to treat approach.

Two interim analyses have been performed.

- At the midpoint of enrollment and randomization (50th patient), a formal interim analysis for safety was performed. Twenty-two patients enrolled into the vaccine arm and 28 enrolled into the control arm were reviewed. There were no grade 4 or 5 toxicities and no differences in toxicities between the arms (Grade 1: 96% vs. 98.5%; Grade 2: 3.2% vs. 1.5%; Grade 3: 0.8% vs 0%, p=0.14). There was no reduction in ejection fraction pre- to post- treatment in either group (vaccine group: 61.1±5.4% vs. 60.1±4.8%,
- A sponsor (Sellas) requested blinded analysis of trial was completed earlier this year. Findings from this review include:
    - Overall Adverse events: The overwhelming proportion of AEs reported were mild, with only 7.8% reporting moderate severity and 0.8% reporting a severe AE (Table 3). Details regarding the toxicities are shown in Table 4.
    - Local toxicity: There were 1286 instances of local toxicity reported, representing 53.6% of all reported toxicities. The majority (.97.4%) instances were grade 1, with 32 reported Grade 2 toxicities and only 2 reported Grade 3 local toxicities. Dose of the vaccine was reduced in 27 instances.
    - Systemic toxicity: There were 1108 instance of systemic toxicity reported. As with the local AEs, the majority (920, 83%) of systemic toxicities were mild, Grade 1 with 163 (14.7%) reported Grade 2 toxicity, 24 (2.2%) reported Grade 3 toxicity and 1 (0.1%) reported Grade 4 toxicity. Vaccine dose was reduced in response to these AEs in 9 instances.

- Twelve recurrences and one death were reported at time of interim analysis. Median time to recurrence was 13.9 months. The one death occurred at 34 months from randomization. Estimated 3-year DFS for the cohort was 82% (Figure 2).
- Timing of the primary endpoint analysis is currently under discussion with the sponsor (Sellas).

Table 2- Tumor features

		Number	Percent of total
Histology	DCIS	3	3%
	Invasive ductal	87	87%
	Invasive lobular	9	9%
	Mixed	1	1%
Tumor grade	Well differentiated	7	7%
	Moderately differentiated	39	39%
	Poorly differentiated	53	53%
	Unknown	1	1%
ER/PR	Negative	26	26%
	Positive	74	74%
HER2 3+	Yes	89	89%
	No	11	11%
Pathologic Nodal Status	Positive	65	65%
	Negative	29	29%
	Unknown	6	6%
Pathologic AJCC Stage	1	4	4%
	1A	18	18%
	1B	2	2%
	2A	23	23%
	2B	17	17%
	3A	24	24%
	3B	2	2%
	3C	10	10%

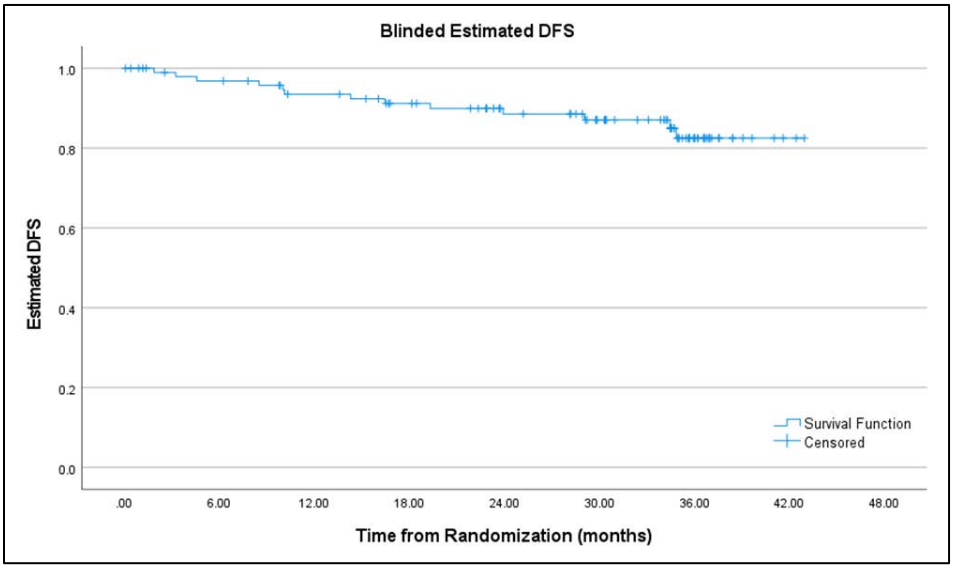
Table 3- Severity of overall adverse events reported

Severity	Frequency	Percent
Not Recorded	1	0.0
Mild	2193	91.4
Moderate	188	7.8
Severe	18	0.8

Table 4-Details of the Overall Reported AEs.

Adverse Event Term	Frequency	Percent		Adverse Event Term	Frequency	Percent
Anorexia	7	0.3		Flushing	1	0.0
Arthralgia	55	2.3		Headache	84	3.5
Back pain	64	2.7		Malaise	43	1.8
Bone pain	39	1.6		Myalgia	58	2.4
Chills	37	1.5		Nausea	37	1.5
Diarrhea	29	1.2		Other (Specify)	667	27.8
Dizziness	12	0.5		Pain (at injection site)	85	3.5
Fatigue	106	4.4		Pruritus	295	12.3
Fever	36	1.5		Skin induration	202	8.4
Injection site reaction-Erythema	505	21.0				
Injection site reaction-warmth	27	1.1				

Figure 2- Estimated DFS for the entire cohort



<u>Specific Aim #2</u>. Evaluate immunologic responses to nelipepimut-S+GM-CSF administered with trastuzumab.

- *In vivo* immune responses are being determined using a delayed type hypersensitivity (DTH) response performed pre-vaccination, one month after completion of the primary vaccination series and 6 months ±

2 weeks after the fourth booster inoculation. These data have been collected and will be analyzed once the fial three patients complete their booster inoculations.

- *In vitro* immune responses will be assessed using a dextramer assay on peripheral blood mononuclear cells, collected at multiple time points including pre-vaccination (R0), after completion of the primary vaccination series (PVS) (R6), prior to the first booster inoculation (RC6/B1), 1 month ± 1 week after the first booster inoculation (RB1) and 6 months ± 2 weeks following the final booster. To date, blood samples have been sent to a research lab at MD Anderson, where they have been processed and stored. Samples are being batched so that dextramer analyses at specific time points will be completed for all patients at the same time.

Specific aim #3. Obtain well annotated blood specimens from patients treated with trastuzumab + nelipepimut-S+GM-CSF or trastuzumab + GM-CSF alone to perform correlative studies.

- Blood samples have been drawn at designated time points. Specimens have been sent to a research lab at MD Anderson, where they have been processed and stored for use in performing correlative studies. The specific correlative studies to be performed are under discussion and additional grant applications to support the conduct of these assays will be submitted.

Opportunities for training and professional development

Nothing to report.

Dissemination of results to communities of interest

Nothing to report.

Plans during next reporting period to accomplish goals

Nothing to report.

4. Impact

Impact on the development of the principal discipline(s) of the project

Nothing to report

Impact on other disciplines

Nothing to report

Impact on technology transfer

Nothing to report

Impact on society beyond science and technology

Nothing to report

5. Changes/Problems

Changes in approach

Adjustments to the clinical trial protocol were made and approved by the IRB (detailed above):

- Initially, enrollment was restricted to patients with expression of HLA-A2 and HLA-A3. Nelipepimut-S was also found to bind to HLA-A24 and HLA-A26. Therefore, eligibility was expanded to also include patients expressing these additional alleles.

- Standard of care was adjusted to include treatment with pertuzumab.

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

Due to the Food and Drug Administration's approval of the drug, pertuzumab (Perjeta®) in the neoadjuvant setting for patients with HER2-positive breast cancer, pCR rates were found to be higher than anticipated, thereby decreasing the number of eligible patients for this study. In order to meet accrual targets within the specified 2-year period, we increased the number of participating sites to 22.

Changes that had a significant impact on expenditures

Nothing to report

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

Nothing to report

6. Products

Publications, conference papers, and presentations

Nothing to report

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

The following personnel report is for the final quarter of the award. All other quarterly personnel efforts have been included in the quarterly technical reports**.**

Name	Isabelle Bedrosian, MD
Project role	Principal Investigator
Research Identifier (e.g. ORCID ID)	ORCID ID: 0000-0002-8775-8361
Nearest person month work	1
Contribution to project	Dr. Bedrosian serves as the PI for the clinical trial
Funding support	Dr. Bedrosian's effort will be supported at 2.5%

Name	Elizabeth A. Mittendorf, MD, PhD
Project role	Co-Investigator

Research Identifier (e.g. ORCID ID)	ORCID ID: 0000-0002-9762-8536
Nearest person month work	1
Contribution to project	Dr. Mittendorf is overseeing the entire project
Funding support	Dr. Mittendorf's effort will be supported at 2%.

Name	Olivia Butler, RN. NBA
Project role	Research Nurse
Nearest person month work	4
Contribution to project	Ms. Butler serves as the lead research nurse for the trial. She conducts all aspects of the study at MD Anderson and serves as a resource for research nurses at other enrolling sites.
Funding support	Ms Butler's salary is supported by the Department of Breast Surgical Oncology

Name	Morgan Yates, RN
Project role	Research Nurse
Nearest person month work	5.8
Contribution to project	Ms. Bonin serves as the secondary research nurse for the trial. She assists Ms. Butler with administering DTH and boosters, and obtaining research blood in addition to assisting with data collection and entry.
Funding support	The remaining salary is covered by the Department of Breast Surgical Oncology

Name	Anne Philips, PhD
Project role	Laboratory Coordinator
Nearest person month work	2.4
Contribution to project	Dr. Philips is overseeing the collection, processing, and storage of PBMC and serum samples. She also oversees the collection of blood for HLA testing and coordinates with the CLIA-certified human flow lab to ensure that testing is completed and results are distributed to participating sites.
Funding support	The award supports 20% effort (2.4 calendar months) for Dr. Philips. Her remaining salary is covered by the Department of Stem Cell Transplantation and Research

Name	Na Qiao, PhD
Project role	Laboratory Coordinator
Nearest person month work	12
Contribution to project	Dr. Na is responsible for conduct and analysis of all the laboratory immune assays .

Change in active other support of the PD/PI(s) or senior/key personnel since the last reporting period

Dr. Bedrosian's active support:

NIH/NCI 1U01CA189240-01 Bedrosian/El-Zein (M-PI) 07/01/2015 – 07/31/2021
Integrative molecular and imaging approaches for risk of subtype specific breast cancer
Objective: To develop an integrated imaging and blood biomarker model for prediction of subtype specific breast cancer risk.

NIH/NCI Alliance NCORP Bertognolli PI) 08/01/2019 – 07/31/2026
NCI Community Oncology Research Program (NCORP) Research Base
Objective: Supports activities relevant to Dr. Bedrosian's role of co-chair of the Alliance Prevention Committee including: i) identify new areas of research opportunity and develop prevention related trials for the NCORP network, ii) oversight of existing trials to help meet accrual targets, iii) participate in NCI Prevention Steering Committee meetings

Dr. Mittendorf 's active support:

5 U54 CA210181-03 (PI: Shen) 08/01/16 - 07/31/21
NIH/Methodist Research Institute
Center for Immunotherapeutic Transport Oncophysics (CITO) (Admin Core)
Objective: To integrate physical sciences with nanotechnology to study transport of immune cells inside the body. The CITO is a collaborative program among three institutions.
Role: Administrative Core Co-Leader

5 U54 CA210181-03 (PI: Shen) 08/01/16 - 07/31/21
NIH/Methodist Research Institute
Center for Immunotherapeutic Transport Oncophysics (Project 1)
Objective: The major goal of Project 1 is to determine the transport phenomena of dendritic cell (DC) vaccines for breast cancer and pancreatic cancer and changes in transport properties of endogenous DCs, effector cells, and macromolecular drugs post-vaccination. This information will be used to improve immune responses in these two cancer models.
Role: Project 1 Co-Leader

SAC1700080 (PI: Mittendorf) 03/26/18 – 03/25/21
Susan G. Komen
Characterization of the immune microenvironment in HER2+ breast cancer to enhance response to standard therapy
Objective: To fully characterize the immune microenvironment in tumors from HER2+ breast cancer patients before and after neoadjuvant chemotherapy + HER2-targeted therapy.
Role: PI

Parker Research Award (PI: Mittendorf) 08/01/18 – 07/31/21
Parker Institute for Cancer Immunotherapy
Objective: To test the hypothesis that ESR1 mutations will harbor immunogenic epitopes in the LBD that can be targeted by vaccination thus eliminating ESR1 mutant clones and restoring sensitivity to endocrine therapy.
Role: PI

SU2C-AACR-CT-11-19 (PI: Mittendorf) 07/01/19 – 06/30/22

Stand Up to Cancer, Catalyst Grant Supported by Genentech

Combination ipatasertib and atezolizumab to prevent recurrence in TNBC

Objective: test the hypothesis that combination therapy with ipatasertib and atezolizumab will target micrometastatic disease after neoadjuvant chemotherapy in triple negative breast cancer patients. A single arm, phase II trial with robust correlative studies will be conducted.

Role: PI

N/A (PI: Mittendorf) 07/01/19 – 6/30/21

Ludwig Center at Harvard

Elucidating the tumor microenvironment (TME) of hormone receptor (HR) positive breast cancer using single cell transcriptomic and spatial profiling to reveal novel immunotherapy-based treatment strategies.

Objective: To fully characterize the TME of HR+ tumors at a single cell level to identify intrinsic mechanisms that may impact the response to immunotherapy in HR+ breast cancer.

Role: PI

2 P50 CA168504-06A1 (PI: Winer) 07/05/19 – 05/31/24

NIH/NCI

Dana-Farber/Harvard SPORE in Breast Cancer

Objective: The Dana-Farber/Harvard Cancer Center (DF/HCC)SPORE in Breast Cancer seeks to improve the prevention and treatment of breast cancer through four integrated, innovative, and highly translational Projects which span all of the major breast cancer subtypes and range in scope from basic and preclinical science to epidemiologic and clinical studies. The purpose of the Tissue and Pathology Core (Core C) is to 1) provide a tissue and blood repository for use by SPORE investigators, 2) to collect, store, process and analyze tissue and blood from participants on SPORE clinical trials with attention to informed consent, patient confidentiality, specimen handling and specimen use 3) to facilitate patient-derived tissue-based translational research for the SPORE and Harvard investigators by providing pathology and technical services integrated with clinical information.

Role: Co-Investigator

Other organizations involved as partners

- SELLAS Life Sciences
  15 W. 38th Street, 10th Floor
  New York, NY, 10018

  SELLAS Life Sciences provides the study drug and funding to Cancer Insight (Contract Research Organization; see below) for their role in the conduct of this study.

- Cancer Insight, LLC
  600 Navarro Street, Suite 500
  San Antonio, TX 78205

  Cancer Insight oversees conduct of the study at sites other than MD Anderson Cancer Center. At these sites, they are responsible for site set-up, training and initiation, study drug distribution, inventory, and accountability; data collections and management through electronic data capture; site management, monitoring and auditing; and financial management through contracting and pass-through cost distribution.

8. Special Reporting Requirements

Not applicable

9. Appendices

None