BREAST CANCER VACCINES: 2019

National Breast Cancer Coalition

The Breast Cancer Deadline 2020

Trial Title	Phase	N	Population	Agent/ Protocol	Outcomes/ Measures	Complete	Sponsorship/ PI	CT#	Comments
Vaccination of Triple Negative Breast Cancer Patients	2 Randomized	102	Neoadjuvant stage II or III TNBC	P10s-PADRE will be administered with MONTANIDE ISA 51 VG as adjuvant/ "standard chemo"	PCR only (no others)	Nov-20	Univ. of Arkansas Issam Makhoul, MD	NCT02938442	Carbohydrate Mimotope-based Vaccine
Open Label Immunotherapy Trial for Breast Cancer (V3-MOMMO)	2 Single Arm	20	Neoadjuvant	V-2 Mommo, pill containing pooled breast cancer antigens obtained from hydrolyzed inactivated blood and tumor tissues of patients with breast cancer	Change in tumor size/LN burden, change in tumor marker from baseline	Nov-19	Immunitor, LLC Aldar Bourinbayar, MD, PhD	NCT03572361	"Successfully tested in published clincial study of liver cancer", Immunitor, LLC is Canadian, trial is in Mongolia
Examining Bioactivity of PVSRIPO in Triple Negative Breast Cancer	1 Early (pilot)	6	Post Neoadjuvant TNBC (but before definitive surgery) with evidence of residual disease (imaging or CBE) in stage II-III, or stage IV with chest wall recurrence	The study drug, PVSRIPO, is the live attenuated oral (Sabin) serotype 1 poliovirus vaccine containing a heterologous internal ribosomal entry site (IRES) derived from the human rhinovirus type 2 (HRV2)	Change in TILs (pre tx biopsy, definitive surgery specimen)	July-21	Istari Oncology, Inc., Duke University, DOD/Shelley Hwang, MD, MPH (Duke) and Darell Bigner, MD, PhD (Istari)	NCT03564782	Booster will be administered 1 week prior to PVSRIPO injection (Day 0), a pre-treatment biopsy is obtained. PVSRIPO is injected into the tumor mass at a dose of 1x10^8 TCID50. On day 14, women will undergo standard-of-care surgical resection of PVSRIPO-treated tumor
Immune Response and Potential Booster for Patients Who Have Received HER2-pulsed DC1	2 Single Arm	40	Post-adjuvant (DCIS, IDC, IBC) previously tx'd with DC1 HER2-pulsed vaccines, low HER immunity	HER2 DC1 Vaccine Booster, injected q3 months x3 into R/L inguinal nodes with U/S guidance	Rate of HER2 Immune Activation (peripheral blood), Rate of restored anti-HER2 CD4 Th1 at 5 years, adverse events	Dec-23	Moffit Ricardo Costa, MD	NCT03630809	
Ability of Dendritic Cell Vaccine to Immunize Melanoma or Epithelial Cancer Patients Against Defined Mutated Neoantigens Expressed by the Autologous Cancer	2 Single Arm	86	Advanced/refractory metastatic melanoma or epithelial cancers	Peptide loaded dendritic cell vaccine	Reponse rate ("percentage of patients who have clinical response"), quantity and quality of circulating antigen-specific T cells (up to 6 year F/U), adverse events	Feb-27	NCI Steven A. Rosenberg, MD	NCT03300843	The National Cancer Institute Surgery Branch (NCI SB) has developed a pipeline for the identification of immunogenic T cell epitopes derived from neoantigens. In recent studies, we identified the neoantigens recognzied by TIL that mediated regression in patients with metastatic cancer using whole exome sequencing of a resected metastatic nodule followed by high throughput immunologic screening, we were able to demonstrate that tumor regressions were associated with the recognition by the administered TIL of unique somatic mutations that occurred in the cancer. We, therefore, aim to use this pipeline to identify immunogenic neoantigens from epithelial cancer patients and to use these defined epitopes for a personalized therapeutic dendritic cell (DC)