BREAST CANCER VACCINES WITH CHECKPOINT INHIBITORS: 2019

National Breast Cancer Coalition

The Breast Cancer Deadline 2020

Trial Title	Phase/N	Population	Vaccine Component	Outcome/ Measure	Checkpoint Inhibitor	Complete	Sponsorship/ PI	CT#	Comments
Neoantigen DNA Vaccine Alone vs. NeoAntigen DNA Vaccine Plus Durvalumab in Triple Negative BC Patients Following Standard of Care Therapy	1, Randomized n=24	Post NeoAdj. TNBC w/o PCR	Neoantigen DNA vaccine x6, at least 21 days apart *(given by the TDS-IM system)	Safety, immune response measured by luminex assay/ELISPOT/ multiparametric flow cytometry for up to 1 yr.	Randomization is + or - durvalumab (anti PD-1). Neoantigen-specific T cell response will be assessed prior in durvalumab arm if present durvalumab q4w	Sept-20	Washington University, Medimmune W. Gillanders, M.D.	NCT03199040	If a neoantigen-specific T cell response is not present, these patients will be replaced but may continue to receive the neoantigen DNA vaccine on study. They will not be transferred to the vaccine-only arm
QUILT-3-057: NANT Neoadjuvant TNBC Vaccine	2 Randomized n= 376 randomization is to plus/minus vaccines and avelumab-control arm is chomeo only	Neo and post-neo TNBC	Multiple vaccines: GI-4000, GI-6207, GI-6301, ETBX-051, and ETBX-061 plus leucovorin, IL-15 complex, engineered NK cells	PCR, EFS, OS, distant metastatic rate, LOcoregional recurrence, QOL (36 months)	Avelumab (anti-PD-L1)		Nantkwest, Inc. Chan Soon-Shiong Institute for Medicine	NCT03554109	Similar nonrandomized phase 1/2 study in advanced disease with n=79: NCT 03387085
Converting HR+ Breast Cancer Into an Individualized Vaccine (CBCV)	2 Randomized (4 arms) n= 100 Duration= 5 mos.: 4 mos. neoadjuvant tx per arm, surgery at 16 wks.	Stage II-III, HR+HER2- post menopuasal BC receiving 4 months neoadjuvant letrazole	Arms 3 & 4 FLT3L (CDX-301, the recombinant human protein by Celldex) will be self-administered subcutaneously, in 5 daily injections week 1 day 1-5.	Tolerability, clinical response rate, pathological response rate, local response rate (tumor specimans for T-cell infiltration at baseline and during treatment), systemic immune response (serial peripheral blood draws)	Arm 2 & 4 Pembrolizumab administered day 12 and q3w until progression or toxicity	Dec-21	Weill Medicall College of Cornell University (4 US trial sites) Silvia Formenti, M.D.	NCT03804944	All arms receive radiation therapy to the breast tumor will begin on week 2 (Day 8, 10, 12), at dose of 8 Gy x 3 fractions, every other day (arm 1 rads alone)
Evaluate Concurrent VRP- HER2 Vaccination and Pembrolizumab for Patients with BC	2 Randomized n=39 3 arms (vaccine or pembro alone, both)	Advanced HER2+/ERPR- receiving trastuzumab plus pertuzumab, with measurable disease and current biopsy	VRP (alphavirus-like replicon particles) containing self amplifying replicon RNA for HER2 q2w x3	Number of TILs and HER2 specific antibodies [24 months], adverse events (24 months), clinical response rate (36 months)	Pembrolizumab (anti PD-1) q3w x 5	Oct-20	Duke, Merck, Sharp & Dohme Corp. H. Kim Lyerly, M.D.	NCT03632941	Tx'd brain mets OK
QUILT-3-067: NANT TNBC Vaccine Molecularly Informed Integrated Immunotherapy in Subjects with TNBC Who have Progressed on or After Standard of Care Therapy	1/2 Nonrandomized n=79	Advanced TNBC		PFS, adverse events, clinical response, clinical benefit, OS. Other: correlative analyses of the neoantigen-specific T-cell response. Potential biomarkers that will be assessed include baseline expression of PD-L1 on tumor infiltrating lymphocytes and tumor, TNBC subtype as determined by gene expression, immune signature as determined by gene expression, mutational landscape, presence and phenotype of neoantigen-sprecific T cells, and neoanbtigen-specific T cell response as measured by multiparameter flow cytometry				NCT03387085	See QUILT/NANT study above
Nab-Paclitaxel and Durvalumab with or without Neoantigen Vaccine in treating patients with metastatic TNBC	2 Randomized n=70	Advanced TNBC, no prior Tx for mets	After gem/carbo run-in experimental arm receives personalized synthetic long peptide vaccine and poly-ICLC		Durvalumab (anti PD-1)	July-19	NCI, Duke William Gillanders, M.D.	NCT03606967	Both arms receive nabpaclitaxel concurrently