Study Title	**A Phase II Trial of the Immunogenicity of a DNA Plasmid-Based Vaccine (STEMVAC) Encoding Th1 Selective Epitopes from Five Antigens Associated with Breast Cancer Stem Cells (MDM2, YB1, SOX2, CDH3, CD105) in Patients with Metastatic Triple-Negative Breast Cancer**
Study Population	Patients with PD-L1-negative metastatic triple negative breast cancer who are receiving chemotherapy in the first or second line. Patients will come into the study on a chemotherapy regimen that was decided by their medical oncologist. This decision and ongoing management is made by the patient's oncologist.
Study Design	This study will accrue 20 patients. All patients will receive the STEMVAC vaccine concurrently with chemotherapy in 1st and 2nd line metastatic setting until disease progression.
Key Eligibility Criteria	• Histologically confirmed triple-negative breast cancer • Tumor is negative for PD-L1 marker. • Patients have not received more than one line of prior therapy in metastatic setting • Must have at least 1 site of disease confirmed by the treating oncologist that could be biopsied during treatment • Willing to undergo up to two serial biopsies while on study • Adequate lab values • Cannot have uncontrolled autoimmune disease requiring active systemic treatment
Study Treatment	STEMVAC will be administered at a 300 mcg dose given intradermally. Patients will receive three vaccine doses administered at 21-28 days intervals (depends on the chemotherapy regimen they are receiving), then 2 booster vaccines 4 and 6 months after vaccine 3, followed by additional booster vaccines every 6 months until cancer progression. Clinical labs will be collected and/or reviewed at the screening visit and prior to every vaccine starting with 1st vaccine. The labs collected per standard of care for the chemotherapy infusion can be used by the research team so as to eliminate repeat lab draws for the patient. Research blood collection for immune analysis, will be collected at screening, at one month after three priming vaccines, prior to the booster vaccines until disease progression. A screening biopsy of metastatic site will be done and then compared to an on-treatment biopsy 1 month after 3rd vaccination. Imaging for disease assessment will be done at Screening within 35 days prior to 1st chemotherapy dose. Follow up CT scans (chest, abdomen, pelvis) performed as part of standard of care, per primary oncologist.
More info	• NCT#: NCT07078604 • www.uwcvi.org
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