



Study Title	A Phase II Study of STEMVAC Vaccine Therapy for Patients with Hormone Receptor Positive Metastatic Breast Cancer
Study Population	Phase II, two arm study of patients with metastatic ER+/PR+/HER2- breast cancer. Up to 40 patients will be enrolled, 20 patients each to Cohort 1 (ET-sensitive) or Cohort 2 (ET-resistant).
Study Design	Patients should be candidates to receive either endocrine therapy plus a CDK4/6 inhibitor or capecitabine as assessed by their primary physician. Patients will receive monthly STEMVAC vaccines for the first three months, then 2 booster vaccines at 6 and 9 months (from 1 st vaccine) followed by additional booster vaccines every 6 months until cancer progression.
Key Eligibility Criteria	• Histologically confirmed hormone receptor positive metastatic breast cancer • HER2-negative or HER2-low • Patients should be receiving the following therapies: • Cohort 1: First or second line of endocrine therapy in combination with a CDK4/6 inhibitor. Patients must have completed at least 2 cycles of CDK4/6 inhibitor. • Cohort 2: Progressed on endocrine-based therapies and after completion of at least 1 cycle of capecitabine • Metastatic disease that is measurable based on RECIST 1.1/PERCIST • Willing to undergo up to two serial biopsies while on study • Adequate lab values • No known autoimmune disease or comorbidities requiring chronic steroids or immunosuppressants
Study Treatment	All patients will receive the STEMVAC 300mcg vaccine concurrently either with endocrine therapy plus a CDK4/6 inhibitor or capecitabine. Patients will receive three vaccines administered 28 (+ 7 days) apart, then 2 booster vaccines at 6 and 9 months (from 1st vaccine) followed by additional booster vaccines every 6 months until cancer progression. Clinical labs will be collected and/or reviewed at the screening visit (up to 30 days before visit) and prior to every vaccine; labs collected per standard of care for allowable treatments can be used by the research team so as to eliminate repeat lab draws for the patient. Research blood draws for immune monitoring will occur: (1) prior to priming vaccine #1, (2) approximately one month after the three priming doses have been completed, (3) prior to each booster vaccine thereafter, (4) end of treatment, and (5) approximately six months after the last vaccine. A biopsy of a metastatic site will be done and compared to an on-treatment tumor biopsy. FES Imaging will be done at Screening and prior to STEMVAC vaccine booster 2 (Cohort 2 only). This will be done as part of the research study as we are looking to see if the additional of the STEMVAC vaccine changes the tumor ER expression profile.
More Information	• NCT#: NCT07112053 • www.uwcv.org
Contact	CVI Coordinators 866.932.8588 cvitrial@uw.edu