CANCER VACCINE INSTITUTE
UW Medicine

| | |
|---|---|
| **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 1st vaccine) followed by additional booster vaccines every 6 months until cancer progression. |
| **Key Eligibility Criteria** | • Histologically confirmed hormone receptor positive metastatic breast cancer<br>• HER2-negative or HER2-low<br>• Patients should be receiving the following therapies:<br>  • **Cohort 1**: First or second line of endocrine therapy in combination with a CDK4/6 inhibitor<br>  • **Cohort 2**: Progressed on endocrine-based therapies and after completion of at least 1 cycle of capecitabine<br>• Metastatic disease that is measurable based on RECIST 1.1<br>• Willing to undergo up to two serial biopsies while on study<br>• Adequate lab values<br>• 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.<br><br>Clinical labs will be collected and/or reviewed at screening 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.<br><br>Research blood draws for immune monitoring will occur: (1) prior to vaccine #1, (2) after the third vaccine (3) prior to each booster vaccine thereafter (4) end of treatment, and (5) approximately six months after the last vaccine.<br><br>A biopsy of a metastatic site will be done and compared to an on-treatment tumor biopsy.<br><br>FES Imaging for 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<br>• www.uwcvi.org |
| **Contact** | CVI Coordinators<br>866.932.8588<br>cvitrial@uw.edu |