**Protocol Title:** Double Blind, Parallel Groups, Controlled, Randomized Phase II Trial to Evaluate Vaccination with Folate Receptor Alpha Peptide Vaccine with GM-CSF as Vaccine Adjuvant Following Oral Cyclophosphamide Versus GM-CSF/Placebo to Prevent Recurrence in Patients with Triple Negative Breast Cancer.

**Target Population:** Females, ages 18 and older with Stage IB-IV Triple Negative Breast Cancer

**Summary:** This randomized phase II trial studies how well multi-epitope receptor Alpha Peptide Vaccine, Sargramostim, and Cyclophosphamide work in treating patients with Triple Negative Breast Cancer.

**Key Inclusion Criteria:**
- Completely resected unilateral or bilateral primary carcinoma of the breast without clinical evidence of disease, negative for ER and PR, and negative for HER2 as defined by one of the four situations delineated below
  - HER2 IHC expression of 0 or 1+ and in-situ hybridization non-amplified
  - HER2 IHC expression of 0 or 1+ and in-situ hybridization not done
  - HER2 IHC expression of 2+ and in-situ hybridization non-amplified
  - IHC not done and in-situ hybridization non-amplified
- Completed planned breast surgeries and any radiation therapy ≥ 30 Days prior to randomization.
- Completed last cycle of chemotherapy ≥ 60 Days but not ≥ 365 Days prior to randomization.
- Patient has at least one of the following:
  - Pathologic N1-3
  - Pathologic T3
  - Neoadjuvant chemotherapy and did not achieve pathologic response at time of surgery
- ECOG performance status of 0 – 1.
- Negative serum pregnancy test done ≤ 14 Days prior to randomization, for women with childbearing potential only.
- Willing to provide tissue and blood samples for research studies.

**Key Exclusion Criteria:**
- Pregnant women, nursing women, or women of childbearing potential who refuse to employ adequate contraception.
- Clinical evidence of local recurrences or distant metastases.
- Inflammatory breast cancer or tumor with deep adherence or cutaneous invasion.
- Known hypersensitivity reaction to GM-CSF.
- History of autoimmune disease per physician discretion.
- Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
- Prior secondary malignancy < 5 Years prior to consent.
- Treatment with systemic corticosteroid or immune-modulators ≤ 30 Days prior to randomization.
- Concurrent treatment with other experimental drugs or any other systemic anticancer therapy.
- Immunocompromised patients and patients that are HIV+ and are receiving antiretroviral therapy.
- Prior or concurrent use of Trastuzumab.

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**For additional information:** [https://www.clinicaltrials.gov/ct2/show/NCT03012100](https://www.clinicaltrials.gov/ct2/show/NCT03012100)