Background

In 2014, there were an estimated 43.5 million cancer survivors in the United States. By 2040, it is projected there will be 19 million cancer survivors (DeSantis et al., 2014), in increases in cancer incidence due to decades of prostate cancer screening, mammography screening, and effective treatments. NeuVax, an immunogenic peptide derived from the extracellular domain of the human epithelial growth factor receptor 2 (HER2), is under investigation in a clinical trial to prevent breast cancer recurrence in these women (www.clinicaltrials.gov) in the adjuvant setting and maintain patients’ “survivor” status.

Methods

NeuVax-positive (neu+) breast cancer patients with HER2-expressing tumors (HER2 2+, 3+), who completed primary standard of care breast cancer therapies (surgery, adjuvant chemotherapy, and targeted agents, as appropriate) demonstrated no evidence of disease, immunologically intact with ECOS-P S-2, and signed informed consent, were enrolled in a Phase 1/2 Study. HLA-A2/A3+ patients were randomized to receive NeuVax vaccine (400 μg) containing NeuVax-S peptide (HLA-A2 restricted) and nelipepimut (nelipepimut-S) for the Prevention of Recurrence in HER2-Expressing Node Positive Breast Cancer Patients (NCT01570036) for 60 months.

Demographics

- **Control (n=53)**: Median age, years 60%
- **Vaccine (n=53):** Median age, years 60%

Clinical Recurrence

- **NeuVax Vaccine**: 2% (2/53) Recurred
- **Control**: 21% (11/53) Recurred

Conclusions

- NeuVax administration concurrently with GM-CSF (NeuVax) appears to be well-tolerated and demonstrated preliminary efficacy in decreasing the rate of recurrence in HER2-positive breast cancer patients.

References

2. ClinicalTrials.gov, accessed, October 18, 2015; NCT01570036; NCT01570056; NCT02297698.
3. VADS: Phase 2 trial of nelipepimut S/Vaccine in Women with OBC Distant Recurrence. NeuVax in conjunction with agents that target antigen release, antigen presentation, priming and activation, T cell trafficking, T cell infiltration, cancer cell recognition, and cancer cell killing are all potential rational combinations for the treatment of a variety of carcinomas.

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