**Background**

Despite recent advances in adjuvant treatment, some HER2 negative patients still relapse. Unlike HER2 positive patients, the benefit of Herceptin® has not been shown in HER2 negative patients. Here we present the final 60-month results of a Phase 1/2 clinical trial vaccinating early stage node-positive breast cancer patients with NeuVax™ (E75, nelipepimut S) and sargramostim following adjuvant chemotherapy and radiation. Patients were treated at Walter Reed Army Medical Center and the Windber Medical Center.

**Methods**

Eligible patients had excised early stage node-positive breast cancer with any level of HER2 expression. After completion of standard care chemotherapy and radiation, patients were enrolled but not randomized; patients were assigned to the vaccine group (VG) only if they were HLA A2+ or A3+. The non-treated patients were followed as a control group (CG). Hormone receptor positive patients received appropriate adjuvant therapy concomitant with vaccine.

NeuVax therapy follows standard of care resection, chemotherapy, radiation for node-positive invasive breast cancer patients.

The Phase 1/2 trial was performed with Phase 1 as a dose escalation/schedule optimization where VG was given 3-6 monthly inoculations of NeuVax (E75, nelipepimut S) with the immuno-adjuvant, sargramostim. The Phase 2 portion utilized the optimal dose and schedule carried forward. Herceptin® became commercially available during the conduct of the trial, and HER2 positive patients were offered this treatment but remained on trial. DFS was summarized by Kaplan-Meier life tables and analyzed by the log-rank test.

**Results**

ITT patients in this phase 1/2 trial favored VG in DFS at 24 months (VG 90.6%, CG 79.9%, p=0.134); at 60 months, the VG continues to have fewer recurrences than the CG (VG 84.7% vs. 77.1%)

When the HER2 positive patients were removed from the population, the Phase 2 HER2 Negative VG had a significantly improved DFS at 24 months (100% vs. 77.4%, p=0.038); at 60 months, VG retains a 20.3% difference (VG 94.4% vs. CG 74.1%).

**Disclosures**

Rosemary Mazanet and Mark Schwartz are employed by Galena Biopharma, Inc. Dunia Ramirez and Phil Lavin are employed by Aptiv Solutions.