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Randomized phase II clinical trial of the anti-HER2 (GP2) vaccine to prevent recurrence in high-risk breast cancer patients: A planned interim analysis.

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Developmental Therapeutics - Immunotherapy

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Abstract Disclosures

Abstract:

Background: A prospective, randomized, multi-center, placebo-controlled, single-blinded, phase II trial was designed to evaluate the safety and clinical efficacy of GP2, a HER2-derived peptide vaccine, in breast cancer patients. **Methods:** Clinically disease-free, node-positive or high-risk node-negative patients (pts) with any level of HER2 expression were enrolled after standard of care therapy. HLA-A2+ pts were randomized to receive GP2 + GM-CSF (VG) or GM-CSF alone (CG). HLA A2- controls from a parallel arm of the study were also eligible for evaluation, the extended CG (ECG). Pts receive 6 monthly intradermal inoculations (R0-R6) during the primary vaccine series followed by four boosters every 6 mos. Immune responses (IR) were measured by delayed type hypersensitivity (DTH) at R0 and R6. This planned interim analysis was performed at 24 months median follow-up. **Results:** We have currently enrolled 172 pts (46, VG; 43, CG; 83 extended CG). There are no differences between groups with respect to age, rate of node positivity, tumor grade, tumor size, ER/PR status, and HER2 over-expression (all p > 0.05). Maximum local toxicity (tox) was similar between the two groups (grade (Gr) 1 and 2: VG 93%, CG 98%; Gr 3: VG 2%, CG 1%). Maximum systemic tox was also similar between the groups (Gr 1 and 2: VG 91%, CG 85%). No Gr 3 systemic tox has been reported. The most frequent systemic reactions are fatigue, headache, and myalgias. IR to GP2 has been robust. DTH is increased from R0 to R6 in the VG (3.0±0.98 to 21.5±4.04

mm, p < 0.01) vs. the smaller increase in CG (2.6±0.89 to 6.0±1.6 mm, p = 0.01). VG DTH at R6 is significantly higher than the CG (21.5 vs 6.0 mm, p < 0.01). The recurrence rate (RR) is decreased in the VG vs CG (4.3% vs. 11.6%, p = 0.41) and VG vs ECG (4.3% vs 9.5%, p = 0.41). In pts with HER2-overexpressing (IHC3+ or FISH+) tumors, the RR is decreased in the VG (0% vs 5% CG, p = 0.28). For TNBC (HER2 low, ER/PR-) pts, the RR is reduced in the VG vs ECG (0% vs 10.6%, p = 0.251). **Conclusions:** The GP2 vaccine is safe and the minimal toxicity is comparable between the VG and CG, suggesting that it is due to GM-CSF. Robust in vivo immune response has correlated with a >50% reduction in breast cancer recurrences in the VG. Clinical trial information: **NCT00524277**.

Abstracts by F. Trappey:

Final pre-specified analysis of the phase II trial of the AE37+GM-CSF vaccine in high risk breast cancer patients to prevent recurrence.
Meeting: 2015 ASCO Annual Meeting | **Abstract No:** 622 | **First Author:** Julia M. Greene
Category: Breast Cancer—HER2/ER - HER2+

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Meeting: 2015 ASCO Annual Meeting | **Abstract No:** e14031 | **First Author:** Julia M. Greene
Category: Developmental Therapeutics—Immunotherapy - Vaccines

Primary analysis of the prospective, randomized, phase II trial of GP2+GM-CSF vaccine versus GM-CSF alone administered in the adjuvant setting to high-risk breast cancer patients.
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