TPS618 **Poster Session**

Phase III study to evaluate the efficacy and safety of GLSI-100 (GP2 + GM-CSF) in breast cancer patients with residual disease or high-risk PCR after both neo-adjuvant and postoperative adjuvant anti-HER2 therapy: Flamingo-01.

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Background: GP2 is a biologic nine amino acid peptide of the HER2/*neu* protein delivered in combination with Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) that stimulates an immune response targeting HER2/neu expressing cancers, the combination known as GLSI-100. Of the 146 patients that have been treated with GLSI-100 over 4 clinical trials, GLSI-100 was well-tolerated and no serious adverse events observed were considered related to the immunotherapy. **Methods:** This Phase III trial is a prospective, randomized, double-blinded, multi-center study. After 1 year of trastuzumab-based therapy, 6 intradermal injections of GLSI-100 or placebo will be administered over the first 6 months and 5 subsequent boosters will be administered over the next 2.5 years. The participant duration of the trial will be 3 years treatment plus 1 additional year follow-up. Study Size – Interim Analysis: Approximately 498 patients will be enrolled. To detect a hazard ratio of 0.3 in invasive breast cancer free survival (IBCFS), 28 events will be required. An interim analysis for superiority and futility will be conducted when at least 14 events have occurred. This sample size provides 80% power if the annual rate of events in placebo patients is 2.4% or greater. Up to 250 non-HLA-A*02 subjects will be enrolled in an open-label arm. Eligibility Criteria: The patient population is defined by these key eligibility criteria: 1) HER2/neu positive and HLA-A*02, 2) Residual disease or High risk pCR (Stage III at presentation) post neo-adjuvant therapy, 3) Exclude Stage IV, and 4) Completed at least 90% of planned trastuzumab-based therapy. Trial Objectives: The trial objectives are to: 1) Determine if GP2 therapy increases IBCFS, 2) Assess the safety profile of GP2, and 3) Monitor immunologic responses to treatment and assess relationship to efficacy and safety. Study Status: The study is actively recruiting and enrolling patients in the US and Europe at up to 150 sites. Contact Information: Greenwich LifeSciences, Inc., Stafford, TX; Email: Flamingo-01@greenwichlifesciences.com; Website: greenwichlifesciences.com Funding: This trial is supported by Greenwich LifeSciences. Clinical trial information: NCT05232916. Research Sponsor: None.