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A randomized, multicenter, placebo-controlled, phase III study to evaluate the efficacy and safety of HER2/neu peptide 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 an FDA-approved immunoadjuvant, Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF, sargramostim, LEUKINE®), that stimulates an immune response targeting HER2/neu expressing cancers.

For the 146 patients that have been treated with GLSI-100 to date over 4 clinical trials, treatment was well-tolerated, and no serious adverse events were observed related to the immunotherapy.

This Phase III trial will explore the use of GLSI-100 as extended-adjuvant therapy to increase invasive disease-free survival in HER2/neu positive breast cancer patients, post-surgery and following the first year of treatment with any trastuzumab-based therapy.

Phase III Trial Status (NCT05232916): The study is actively recruiting and enrolling patients in the US and Europe at up to 150 sites.

TRIAL DESIGN

This Phase III trial is a prospective, randomized, double-blinded, multi-center study. After 1 year of trastuzumab-based therapy or an approved biosimilar, 6 intradermal injections of GLSI-100 or saline placebo will be administered for the first 6 months as the primary immunization series followed by 5 boosters over the next 2.5 years for a total of 11 injections over 3 years of treatment. The participant duration of the trial will be 3 years treatment plus 1 year follow-up for a total of 4 years following the first year of treatment with trastuzumab-based therapy. An interim analysis is planned, and patients will be stratified based on prior treatment.

FUNDING & CONFLICT OF INTEREST

This trial is supported by Greenwich LifeSciences. Snehal Patel is an employee, owns stock/options, and is a board member of Greenwich LifeSciences.

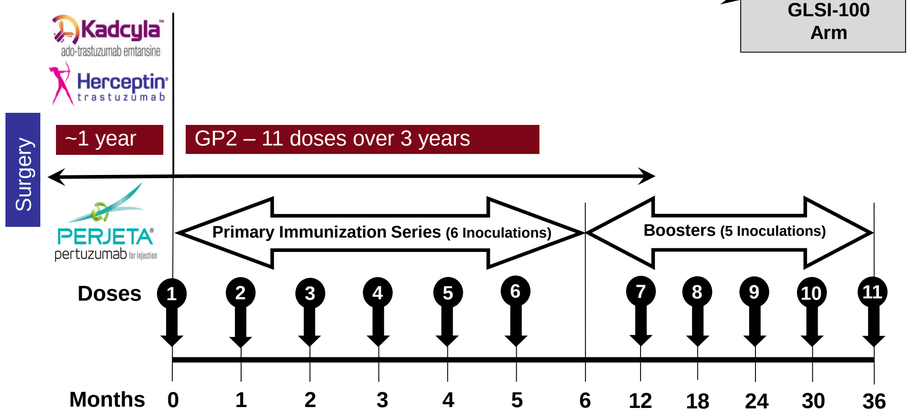
FLAMINGO-01 SCHEMA

Major Screening Criteria:

- **HER2/neu Positive Breast Cancer**
- **Residual disease post neo-adjuvant therapy and surgery**
- **pCR if Stage III at presentation**
- **HLA-A*02 Positive**

Stratified by:

- **Residual disease/pCR**
- **Hormone receptor status**
- **Geographic region**



- **Measure immune response by Delayed Type Hypersensitivity (DTH) skin test and/or immunological assays (potential biomarkers) from blood**
- **Peak immune response expected after 6 months and completion of first 6 doses**

PATIENT POPULATION

The patient population is defined by these key eligibility criteria:

- HER2/neu positive and HLA-A*02 positive
- Residual disease or high risk pCR (Stage III at presentation) post appropriate neo-adjuvant therapy
- Exclude Stage IV
- Completed at least 90% of planned trastuzumab therapy

TRIAL OBJECTIVES

1. To assess efficacy of GLSI-100 in HER2/neu breast cancer subjects who have high risk of recurrence. Assessed primarily by invasive breast cancer free survival (IBCFS).
2. To assess secondary measure of efficacy (IDFS, DDFS, OS, QLQ-C30 and FACT-GP5).
3. To monitor the in vitro and in vivo immunologic responses to therapy and correlate these responses with the clinical outcomes.
4. To assess safety and tolerability of GLSI-100.

STUDY SIZE – INTERIM ANALYSIS

Approximately 498 subjects will be enrolled. To detect a hazard ratio of 0.3 in IDFS, 28 events will be required. An interim analysis for superiority and futility will be conducted when at least half of those events, 14, have occurred. This sample size provides 80% power if the annual rate of events in placebo-treated subjects is 2.4% or greater. Approximately 250 additional subjects will be enrolled in a non-HLA-A*02 arm.

CONTACT INFORMATION

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