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Preliminary delayed-type-hypersensitivity immune response results from open-label arm of ongoing 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

This Phase III trial, FLAMINGO-01, is a prospective, randomized, double-blinded, multi-center study (NCT05232916) in HLA-A*02 patients at approximately 160 sites in the US and Europe. A third non-randomized arm of approximately 250 non-HLA-A*02 patients is now fully enrolled and preliminary immune response data is presented below.

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.

METHODS

After standard of care neoadjuvant and adjuvant therapy, 6 intradermal injections of GLSI-100 will be administered over the first 6 months and 5 subsequent boosters will be administered over the next 2.5 years. The patient duration of the trial will be 3 years treatment plus 1 additional year follow-up. Immune responses to GP2 were measured over time using delayed-type-hypersensitivity (DTH) skin tests and injection site reactions (ISRs). The patient population is defined by these key eligibility criteria: 1) HER2/neu positive and HLA, 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.

Delayed Type Hypersensitivity tests (DTH) were conducted at various times throughout the study. A small amount of GP2 alone, without the adjuvant GM-CSF, is placed under the patient's skin and 48 to 72 hours later, the test site is assessed for evidence of redness or induration.

CONTACT INFORMATION

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https://clinicaltrials.gov/ct2/show/NCT05232916

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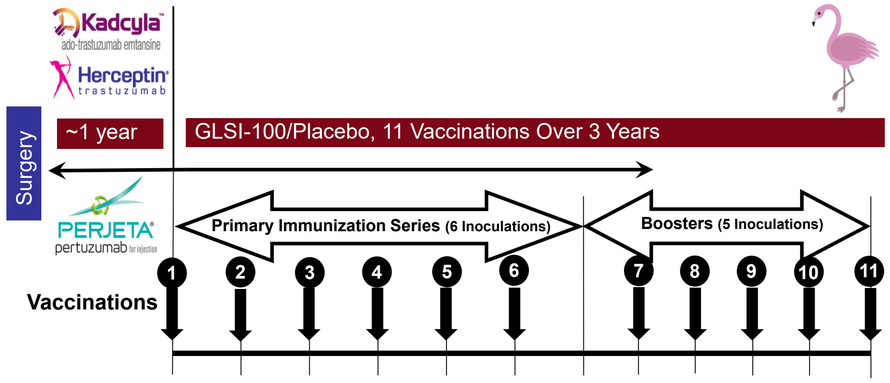
FLAMINGO TREATMENT



- **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 vaccinations**

TABLE 1: DTH IMMUNE RESPONSE TO GP2 BY HLA

HLA-A Allele Present[1]	Number of Patients[2]	Baseline Reaction (Redness) n (%)	Reaction at Month 4 or 6 (Redness) n (%)	% Increase from Baseline to Month 4 or 6
All non-HLA-A*02[3]	191	10 (5.2)	39 (20.4)	290%
HLA-A*01	65	5 (7.7)	18 (27.7)	260%
HLA-A*03	54	1 (1.9)	8 (14.8)	700%
HLA-A*11	29	2 (6.9)	6 (20.7)	200%
HLA-A*24	52	2 (3.8)	8 (15.4)	300%
HLA-A*29	28	2 (7.1)	4 (14.3)	100%
HLA-A*30	16	3 (18.8)	6 (37.5)	100%
HLA-A*68	25	2 (8.0)	6 (24.0)	200%

[1] Patients with at least one allele. Double allele patients are reported once. Patients with 2 different alleles reported twice under each allele.
[2] Patients with complete paired data (baseline and Month 4 or 6 assessment)
[3] Patients without an HLA-A*02 allele treated in open-label arm

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.

RESULTS

Patients enrolled in the open-label study (n=247) were vaccinated with GLSI-100 and continue in treatment and follow-up. A DTH reaction (redness and/or induration) was used to assess in vivo immune responses in patients. The DTH orthogonal mean was also measured 48-72 hours after injection but is not reported here.

In this preliminary data analysis, there was a significant increase in percentage of patients experiencing a DTH reaction (redness) in month 4 or month 6 compared to baseline. There were 191 patients with both baseline and month 4 or 6 assessment. The frequency of DTH reactions increased by approximately 4x (290%) in the total open-label non-HLA-A*02 population, increasing from 5.2% of the patients experiencing a DTH reaction at baseline, prior to any GLSI-100 administration, to 20.4% of the patients experiencing a DTH reaction in month 4 or month 6 (McNemar, $p < 0.001$). As reported in Table 1, each HLA-A type exhibited more frequent immune reactivity after treatment with GLSI-100 than at baseline with frequency increasing from 100% to 700%.

Baseline DTH reaction prior to any treatment suggests that GP2 may be a natural antigen.

Analysis excludes patients in the HLA-A*02 arms, which may have other non-HLA-A*02 alleles.

The study is ongoing and data collection and cleaning continue so final results may vary.

CONCLUSIONS

The increase in the incidence of DTH reactions over time found in this preliminary analysis of GLSI-100 treated non-HLA-A*02 patients shows that GLSI-100 treatment should not be limited to the HLA-A*02 genotype. Subjects treated with GLSI-100 were increasingly able to mount an immune response to GP2 as evidenced in this preliminary data. Future investigations may explore the use of immune responses to assess: correlation of DTH to ISRs, immunogenicity of GLSI-100 by specific HLA type, timing of boosters to sustain immunity, clinical site performance, and the discontinuation of treatment for non-responders.