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FLAMINGO-01

Preliminary injection site reaction 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.

Injection Site Reactions (ISR) were assessed 48 to 72 hours after vaccination. The site is assessed for evidence of erythema (redness) or induration, including measurements of diameters of both. Each patient presents two alleles and results are reported for both.

CONTACT INFORMATION

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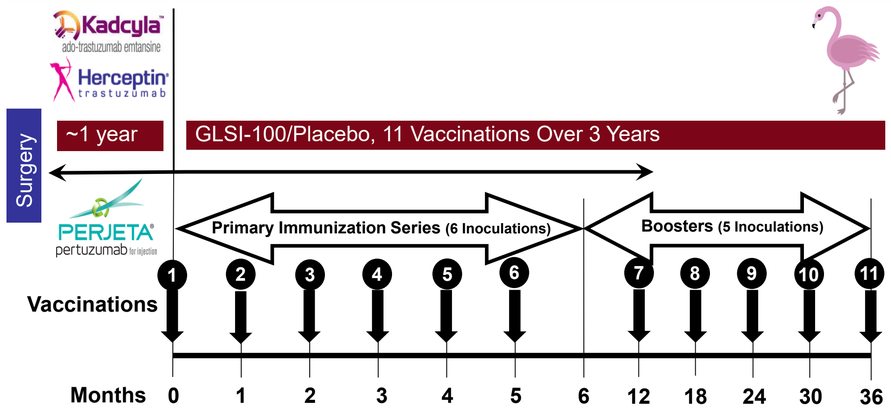
TABLE 1: INJECTION SITE REACTION TO GLSI-100 BY HLA

HLA-A Allele Present[1]	Number of Patients[2]	Erythema: Baseline Reaction n (%)	Erythema: Reaction at Dose 4, 5 or 6 n (%)	Erythema: % Increase Baseline to Dose 4, 5 or 6	Induration: Baseline Reaction n (%)	Induration: Reaction at Dose 4, 5 or 6 n (%)	Induration: % Increase Baseline to Dose 4, 5 or 6
All non-HLA-A*02[3]	**208**	**42 (20.2)**	**115 (55.3)**	**174%**	**31 (14.9)**	**72 (34.6)**	**132%**
HLA-A*01	68	10 (14.7)	38 (55.9)	280%	9 (13.2)	24 (35.3)	167%
HLA-A*03	57	12 (21.1)	30 (52.6)	150%	6 (10.5)	16 (28.1)	167%
HLA-A*11	33	6 (18.2)	19 (57.6)	217%	6 (18.2)	11 (33.3)	83%
HLA-A*24	54	12 (22.2)	30 (55.6)	150%	12 (22.2)	24 (44.4)	100%
HLA-A*29	33	7 (21.2)	18 (54.5)	157%	5 (15.2)	8 (24.2)	60%
HLA-A*30	18	4 (22.2)	9 (50.0)	125%	2 (11.1)	5 (27.8)	150%
HLA-A*68	31	6 (19.4)	20 (64.5)	233%	5 (16.1)	9 (29.0)	80%

[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 Dose 4, 5 or 6 assessment)
[3] Patients without an HLA-A*02 allele treated in open-label arm

FLAMINGO TREATMENT



- **Measure immune response by Delayed Type Hypersensitivity (DTH) skin test and/or immunological assays. Peak immune response expected after 6 months and completion of first 6 vaccinations**

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. Injection site reactions, erythema (redness) and induration were assessed at various time points and represent an in vivo immune response in patients. In this preliminary data analysis, there were 208 participants with both baseline and dose 4, 5 or 6 assessment. The study is ongoing and data collection and cleaning continue so final results may vary.

Erythema: There was a significant increase in the percentage of patients experiencing erythema ISRs after the 4th, 5th or 6th vaccination compared to the ISRs from the 1st vaccination. In this preliminary analysis, the frequency of ISRs increased significantly from 20.2% of the patients experiencing an ISR after the first vaccination to 55.3% of the patients experiencing an ISR after the 4th, 5th or 6th vaccination (McNemar $p < 0.001$), representing an increase of 2.7x or 174%.

Induration: There was a significant increase in the percentage of patients experiencing induration ISRs after the 4th, 5th or 6th vaccination compared to the ISRs from the 1st vaccination. In this preliminary analysis, the frequency of ISRs increased significantly from 14.9% of the patients experiencing an ISR after the first vaccination to 34.6% of the patients experiencing an ISR after the 4th, 5th or 6th vaccination (McNemar $p < 0.001$), representing an increase of 2.3x or 132%.

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 60% to 280%.

CONCLUSIONS

The increase in the incidence of injection site reaction immune response 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.