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Planned GLSI-100 (GP2 + GM-CSF) Phase III Clinical Trial

A Breakthrough Targeted Immunotherapy to Prevent Breast Cancer Recurrences

NASDAQ: **GLSI**

Snehal Patel, CEO

Greenwich LifeSciences

Image: T-cells targeting cancer cell

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GLSI-100 (GP2 + GM-CSF) Executive Summary

- Flamingo-01 - Current Phase III Trial with Interim Analysis: 9 amino acid HER2/*neu* peptide + GM-CSF immunotherapy for breast cancer in adjuvant/neoadjuvant setting (post-surgery) in HER2/*neu* 3+, HLA-A2 patients in Y2 following Herceptin or Kadcyla, led by Baylor & consortium of prominent cancer centers
- Conservative design of Phase III trial to reproduce Phase IIb results
- Phase IIb Trial Results: Randomized, multi-center (16 centers), placebo-controlled, **0% recurrences over median 5 years follow-up**, if fully immunized, versus 11% placebo recurrence rate in 96 patients (*p = 0.0338*), peak immunity after 6 months, minimal to no side effects, no SAEs attributable to GP2, led by MD Anderson Cancer Center
- Potential Opportunities to Expand Market:
  - HER2/*neu* 1-2+ patients with Herceptin - increase market from 25% to 75%
  - Other HLA types – increase from 40-50% up to 80% of all patients
  - Combination with CD4/CD8 peptides and checkpoints
  - Other HER2/*neu* cancers
- NASDAQ Ticker “GLSI”: Raised $36.5m since IPO

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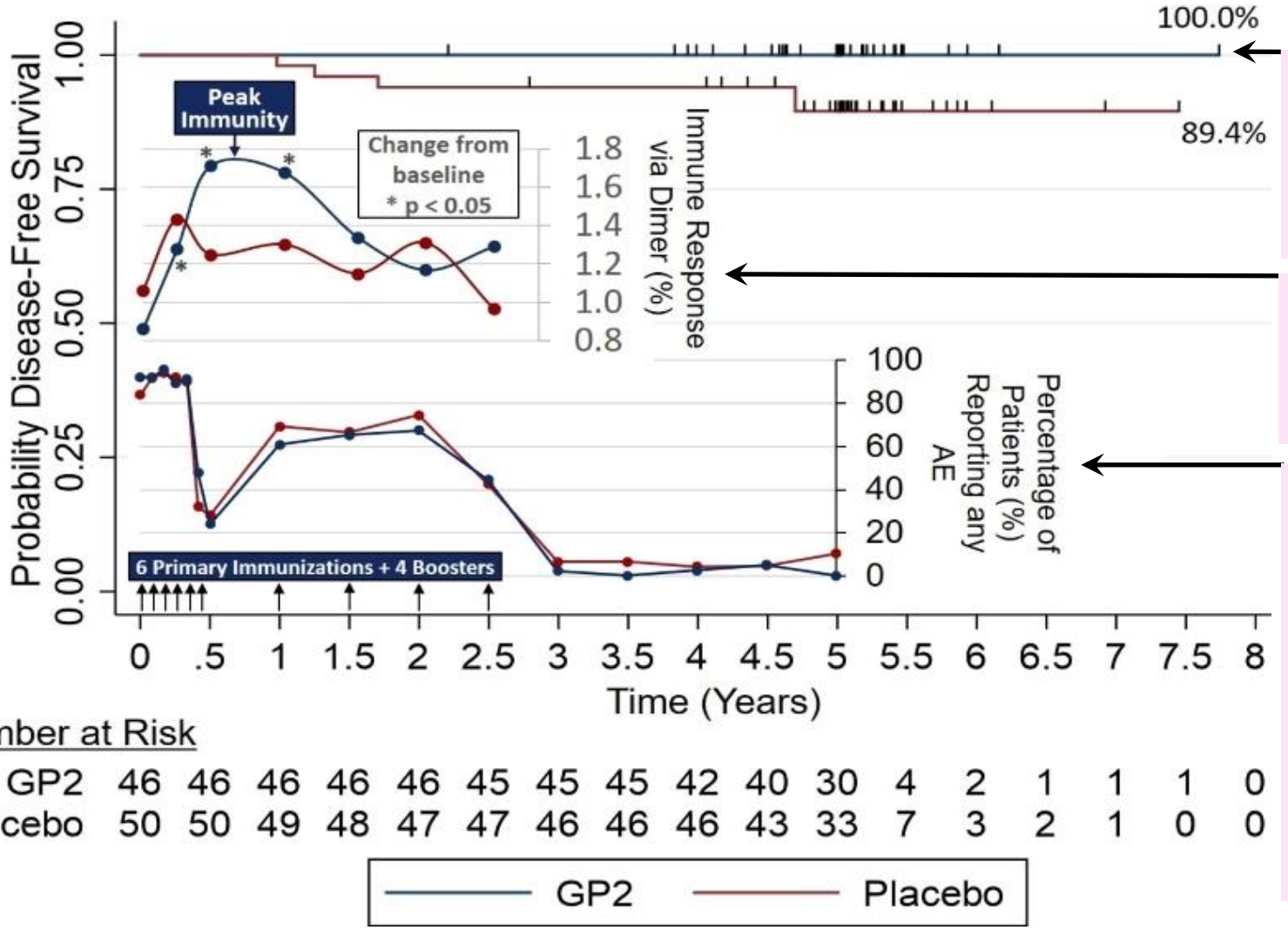
5 Year Data Set of GP2 Phase IIb Trial is Complete

HER2 3+ (Positive) Patients who Completed the Primary Immunization Series (PIS)



100% Disease Free Survival, 0% Metastatic Breast Cancer Recurrences

Peak Immunity After 6 Months & PIS

Injection Site & Systemic Adverse Events (AE) are Positive Sign of Immune Response – No SAEs attributable to GP2 treatment

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Breast Cancer – *Still* a Substantial Unmet Need

- ***Unmet Need is to address the 50% of recurring patients who do not respond to Herceptin or Kadcyla – an opportunity for GP2.***
- ***Adjuvant Setting: Following breast cancer surgery, HER2/neu 3+ patients receive Herceptin in the first year and then hope that their breast cancer will not recur, with the odds of recurrence slowly decreasing over the first 5 years. Herceptin reduces recurrence rates from 25% to 12%.***
- ***Neoadjuvant Setting: Kadcyla was just approved for use in patients with residual disease determined via pCR at time of surgery. Kadcyla reduces recurrence rates from 22% to 11%.***
- ***Neither Perjeta or Nerlynx fully address this unmet need, even in their most efficacious subpopulations.***

GP2 Addresses Unmet Need: GP2 & GM-CSF starting in Year 2 act synergistically with Herceptin to prevent cancer recurrences, if fully immunized, reducing recurrence rates from **11%** to **0%** at median 5 years follow-up (*p = 0.0338*), with minimal to no side effects & no SAEs.

In the initial GP2 indication, approximately 17,000 new patients could be treated per year, saving up to 1,500 to 2,000 lives per year.

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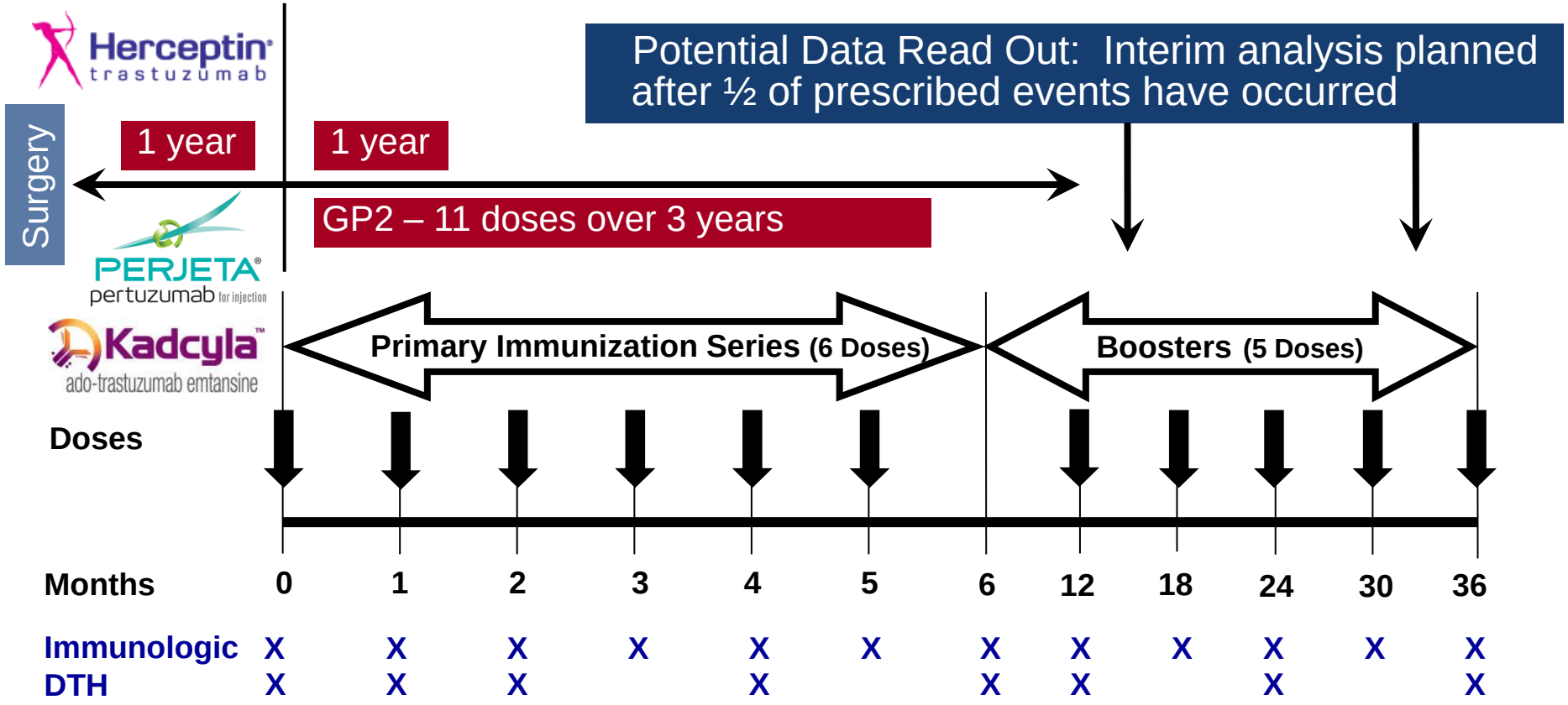
pCR = pathologic complete response, the lack of all signs of cancer in tissue samples remove during surgery or biopsy due to Neoadjuvant treatment.

GP2 Phase III Clinical Trial Dosing



- Study allows prior use of pertuzumab, trastuzumab, and ado-trastuzumab emtansine and concurrent neratinib
- Final DTH/immunologic assays at 48 months and at time of recurrence

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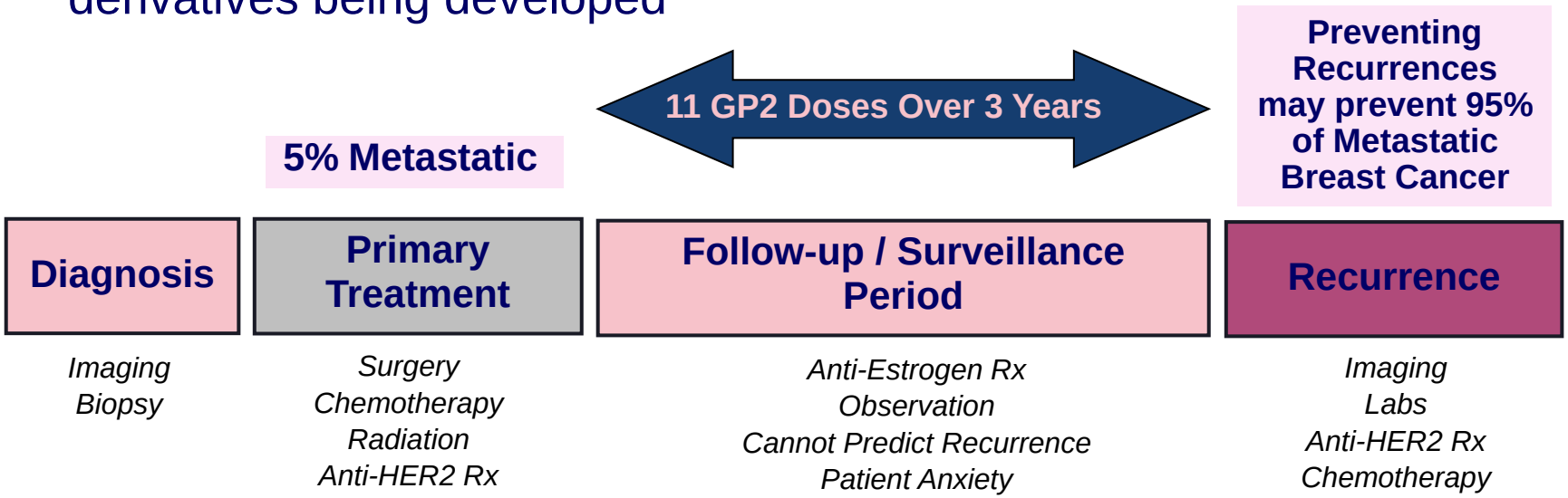
GP2 Market Positioning & Feedback from KOLs

- As only injection site reactions were observed (which speaks to the immunogenicity of GP2) and with no SAEs attributable to GP2, GP2 can be positioned as the final treatment for patients post surgery
- Patients are seeking a de-escalation and a return to normal life free of toxic treatments, especially if the chance of recurrence is reduced substantially
- GP2 can be the treatment that will naturally overlap with or follow Herceptin, Kadcyla, or Enhertu or any of the other Herceptin derivatives being developed



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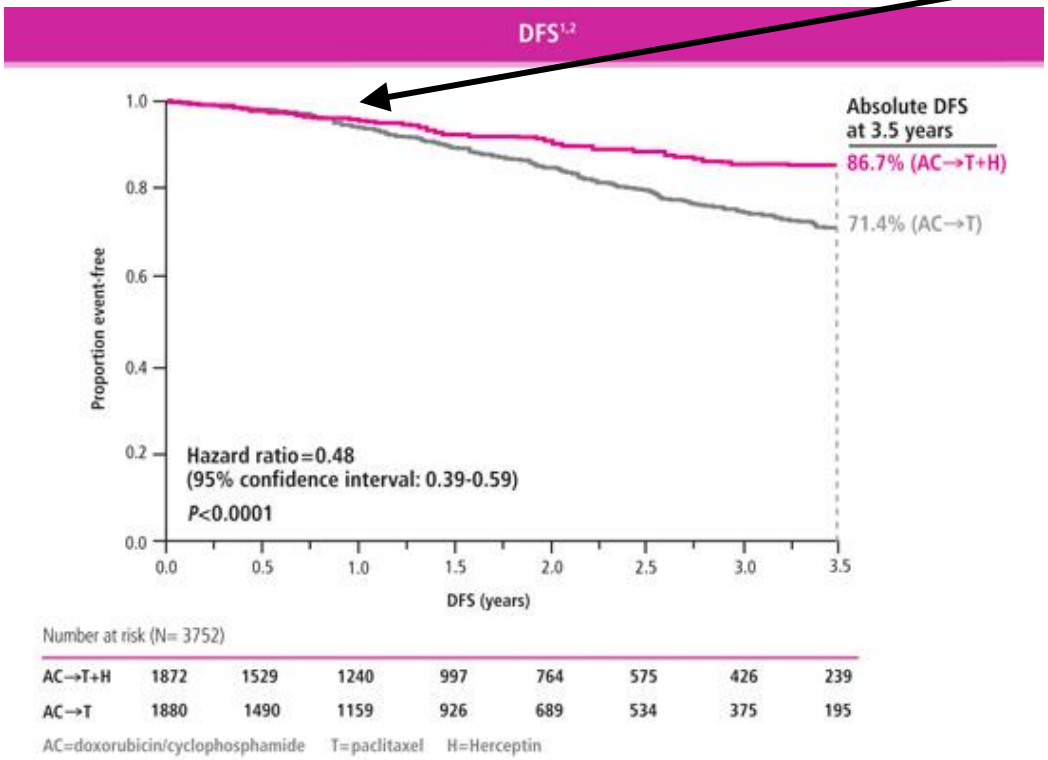
Synergy with Herceptin Alone ** 0% Metastatic Cancer Recurrences

** 5 Year 100% Disease Free Survival without use of Kadcyla, Perjeta, Nerlynx, Enhertu, or Tukysa

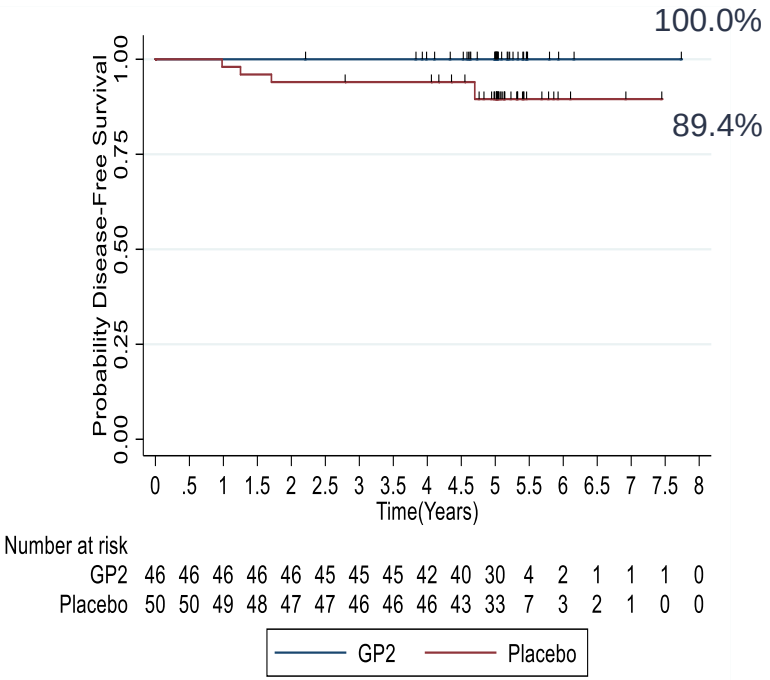
Herceptin Approved for Adjuvant Treatment of HER2/*neu* 3+ Breast Cancer



Joint Analysis Trial

*DFS – Disease Free Survival

Phase IIb Results for GP2 Target Population, if Fully Immunized (median 5 years follow-up)



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GP2 Clinical Data:

GP2 is Immunogenic & Clinically Effective

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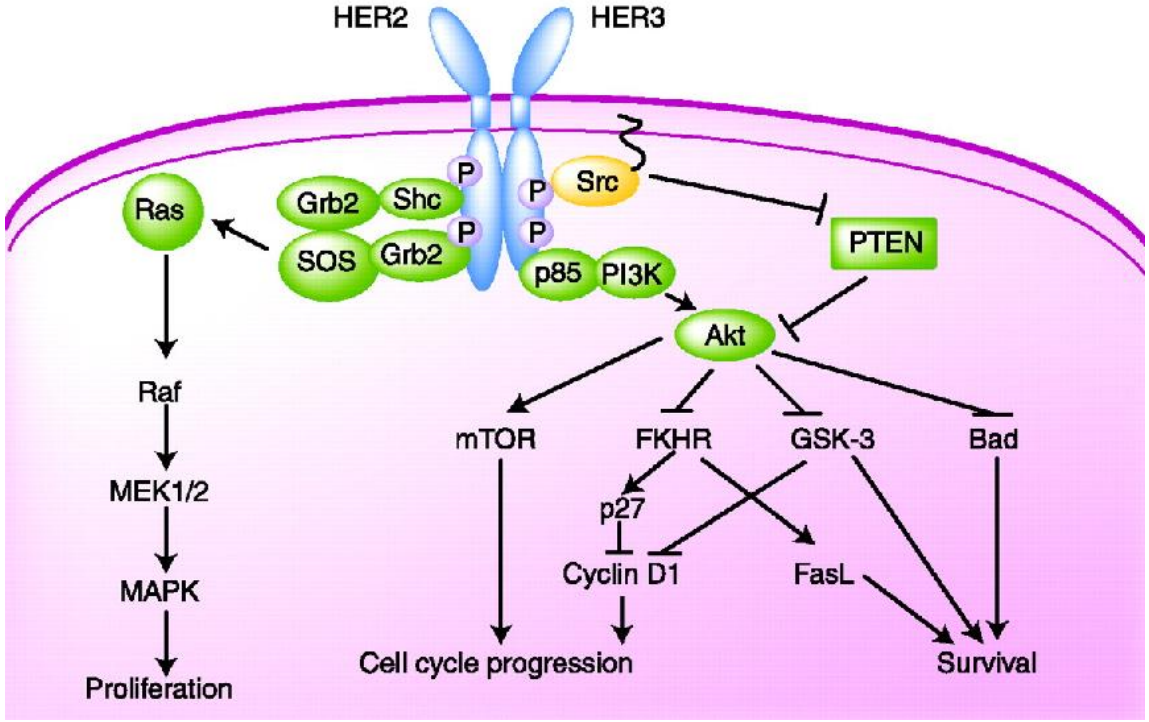
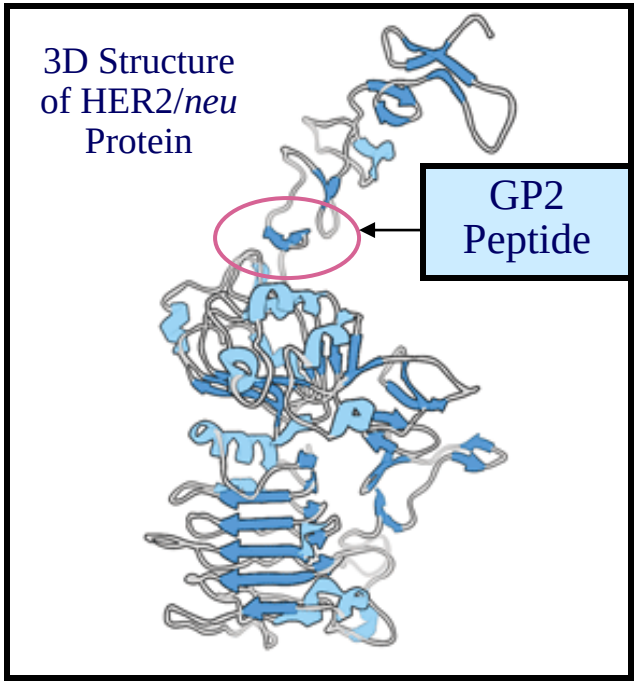
HER2/*neu* Signaling Pathway Well Studied

- HER2/*neu* pathway activates cancer cell proliferation
- Overexpression of HER2/*neu* correlates strongly with aggressive cancers



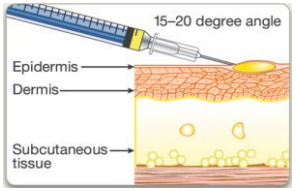


GP2 Product Description & Mechanism of Action

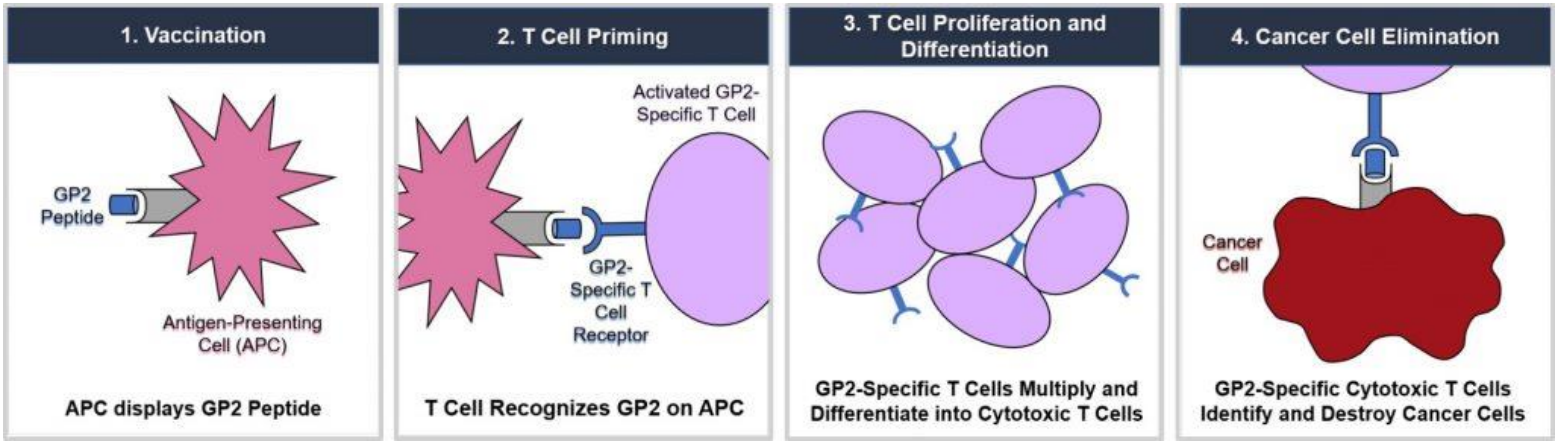
- 9 amino acid transmembrane peptide segment of HER2/*neu* protein
- Intradermal injection in combination with an FDA-approved immunoadjuvant GM-CSF, following 1st year of Herceptin treatment in Adjuvant Setting

Leukine® sargramostim

Herceptin® trastuzumab



- Given once per month for six months followed by 5 booster doses every 6 months = 11 doses over 3 years
- Mechanism of Action: 4 primary steps, followed by a secondary epitope spreading & broader immune response



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Summary of GP2 Completed Trials - N=146 GP2-Treated Patients to Date with No SAEs Attributable to GP2

Study	Design and Control	Product, Dose, and Route	Regimen	Number of Subjects	Population	Duration of Follow-Up
Phase 1b 04-20017, (MCHL-SG (40-38a))	3x3 Dose-escalation	• GP2 at 100, 500, 1000mcg • GM-CSF at 250mcg (reduced to 125mcg in many subjects) • Intradermal	6 doses, every 3-4 weeks	18	• Breast cancer • HER2/neu 1-3+ • HLA-A*02 • Node negative	Primary safety follow-up for the duration of treatment + 30 days.
Phase 1b (C.2008.146)	3x3 Dose-escalation	• GP2+GM-CSF • GP2 at 100, 500, 1,000mcg • GM-CSF at 125, 250mcg • Intradermal • Concurrent iv trastuzumab	6 doses, every 3 weeks	17	• Breast cancer • HER2/neu 1-3+ • HLA-A*02 and HLA-A*03	Primary safety follow-up for the duration of treatment + 30 days.
Phase 1	3x3 Dose-escalation	• GP2+AE37+GM-CSF • GP2 at 100, 250, 500mcg • AE37 at 100, 250, 500mcg • GM-CSF at 125mcg • Intradermal	6 doses, 1 month apart	22	• Breast and ovarian cancer • HER2/neu 1-3+ • HLA-A*02 and HLA-A*03	1.5 years
Phase 2b (C.2007.098)	Randomized, Single-Blind	• GLSI-100 or GM-CSF alone • GP2 500mcg • GM-CSF 125mcg	• 6 doses, 1 month apart • 4 boosters beginning at 12 mo. then every 6 mo.	180 GLSI-100 (n = 89) GM-CSF alone (n = 91)	• Breast cancer • HER2/neu 1-3+ • HLA-A*02 • Node-positive and High-risk node-negative	5 years

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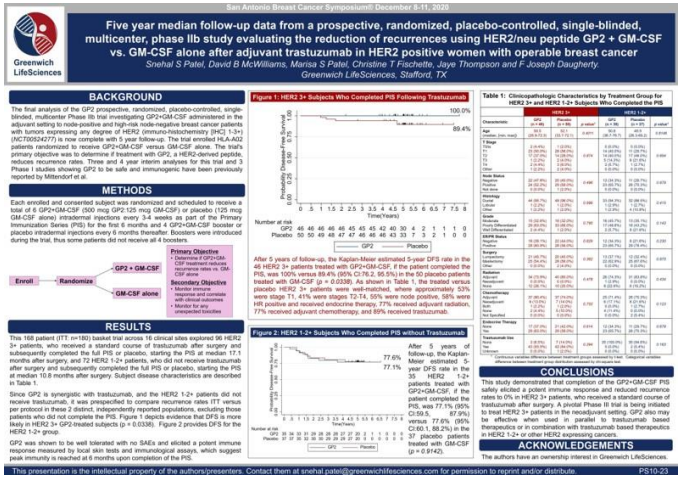
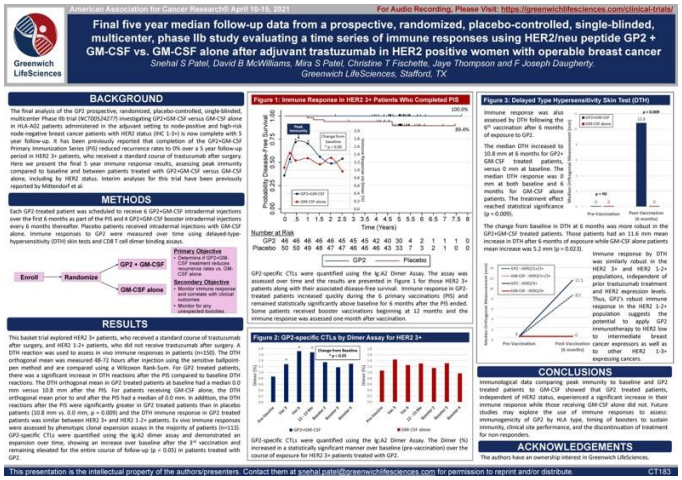
2020-2021 - Four Posters Highlighting Efficacy, Mechanism of Action, Safety, & Prognostic Factors

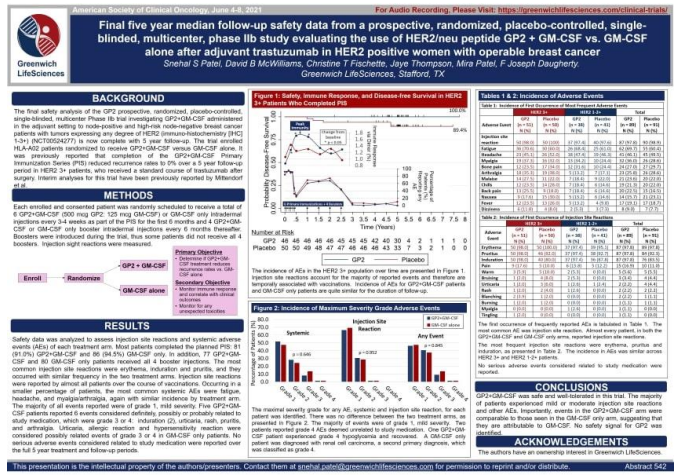
2020 San Antonio Breast Cancer Symposium (SABCS)
0% Recurrences Over 5 Years in Phase IIb Trial



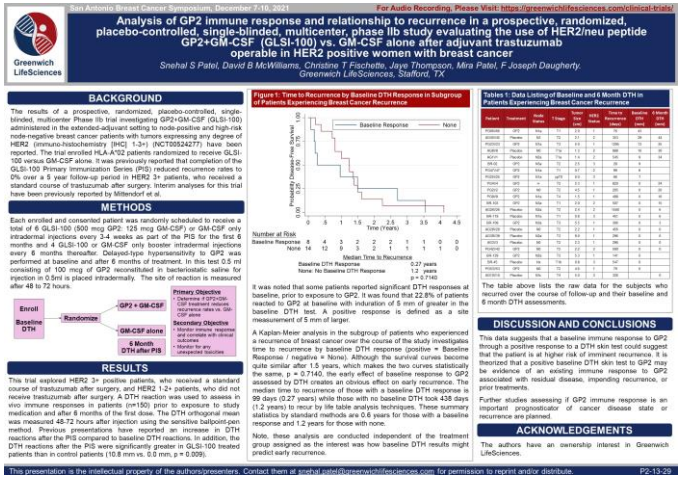
2021 American Association for Cancer Research (AACR)
Immune Response Supports Mechanism of Action



2021 American Society of Clinical Oncology (ASCO)
Injection Related Immune Reactions, No GP2 Related SAEs



2021 SABCS Baseline GP2 Immune Response
May Predict Faster & Earlier Recurrence



SABCS 2020 – Populations Well Balanced

Table 1: Clinicopathologic Characteristics by Treatment Group for HER2 3+ and HER2 1-2+ Patients Who Completed the 6 Month Primary Immunization Series (PIS)

The treated versus placebo HER2 3+ patients were well-matched, where approximately 53% were stage T1, 41% were stages T2-T4, 55% were node positive, 58% were hormone receptor positive and received endocrine therapy, 77% received adjuvant radiation, 77% received adjuvant chemotherapy, and 89% received trastuzumab. There were no recurrences in the 10-11 HER2 3+ patients who did not receive trastuzumab.

[1] Continuous variables difference between treatment groups assessed by t-test. Categorical variables difference between treatment group distribution assessed by chi-square test.

	HER2 3+			HER2 1-2+		
Characteristic	**GP2 (n = 46)**	**Placebo (n = 50)**	***p* value[1]**	**GP2 (n = 35)**	**Placebo (n = 37)**	***p* value[1]**
Age (median, [min, max])	50.5 (26.9-72.3)	52.1 (33.7-72.1)	*0.4011*	50.8 (36.7-76.7)	49.9 (26.3-69.2)	*0.8146*
T Stage						
T0/is	2 (4.4%)	1 (2.0%)		0 (0.0%)	0 (0.0%)	
T1	23 (50.0%)	28 (56.0%)		14 (40.0%)	11 (29.7%)	
T2	17 (37.0%)	14 (28.0%)	*0.874*	14 (40.0%)	17 (46.0%)	*0.654*
T3	1 (2.2%)	2 (4.0%)		5 (14.3%)	8 (21.6%)	
T4	2 (4.4%)	3 (6.0%)		2 (5.7%)	1 (2.7%)	
Other	1 (2.2%)	2 (4.0%)		0 (0.0%)	0 (0.0%)	
Node Status						
Negative	22 (47.8%)	20 (40.0%)	*0.496*	12 (34.3%)	11 (29.7%)	*0.679*
Positive	24 (52.2%)	29 (58.0%)		23 (65.7%)	26 (70.3%)	
Not done	0 (0.0%)	1 (2.0%)		0 (0.0%)	0 (0.0%)	
Histology						
Ductal	44 (95.7%)	48 (96.0%)	*0.996*	33 (94.3%)	32 (86.5%)	*0.415*
Lobular	1 (2.2%)	1 (2.0%)		1 (2.9%)	1 (2.7%)	
Other	1 (2.2%)	1 (2.0%)		1 (2.9%)	4 (10.8%)	
Grade						
Moderate	15 (32.6%)	16 (32.0%)	*0.795*	16 (45.7%)	13 (35.1%)	*0.143*
Poorly Differentiated	29 (63.0%)	33 (66.0%)		17 (48.6%)	16 (43.2%)	
Well Differentiated	2 (4.4%)	1 (2.0%)		2 (5.7%)	8 (21.6%)	
ER/PR Status						
Negative	18 (39.1%)	22 (44.0%)	*0.629*	12 (34.3%)	8 (21.6%)	*0.230*
Positive	28 (60.9%)	28 (56.0%)		23 (65.7%)	29 (78.4%)	
Surgery						
Lumpectomy	21 (45.7%)	20 (40.0%)	*0.362*	13 (37.1%)	12 (32.4%)	*0.675*
Mastectomy	25 (54.4%)	28 (56.0%)		22 (62.9%)	25 (67.6%)	
Other	0 (0.0%)	2 (4.0%)		0 (0.0%)	0 (0.0%)	
Radiation						
Adjuvant	34 (73.9%)	40 (80.0%)	*0.478*	26 (74.3%)	31 (83.8%)	*0.434*
Neoadjuvant	0 (0.0%)	0 (0.0%)		1 (2.9%)	0 (0.0%)	
None	12 (26.1%)	10 (20.0%)		8 (22.9%)	6 (16.2%)	
Chemotherapy						
Adjuvant	37 (80.4%)	37 (74.0%)		25 (71.4%)	26 (70.3%)	
Neoadjuvant	6 (13.0%)	7 (14.0%)	*0.753*	6 (17.1%)	8 (21.6%)	*0.123*
Both	1 (2.2%)	1 (2.0%)		0 (0.0%)	1 (2.7%)	
None	2 (4.4%)	5 (10.0%)		4 (11.4%)	0 (0.0%)	
Not Specified	0 (0.0%)	0 (0.0%)		0 (0.0%)	2 (5.4%)	
Endocrine Therapy						
None	17 (37.0%)	21 (42.0%)	*0.614*	12 (34.3%)	11 (29.7%)	*0.679*
Yes	29 (63.0%)	29 (58.0%)		23 (65.7%)	26 (70.3%)	
Trastuzumab Use						
None	3 (6.5%)	7 (14.0%)		35 (100.0%)	35 (94.6%)	
Yes	43 (93.5%)	42 (84.0%)	*0.294*	0 (0.0%)	2 (5.4%)	*0.163*
Unknown	0 (0.0%)	1 (2.0%)		0 (0.0%)	0 (0.0%)	

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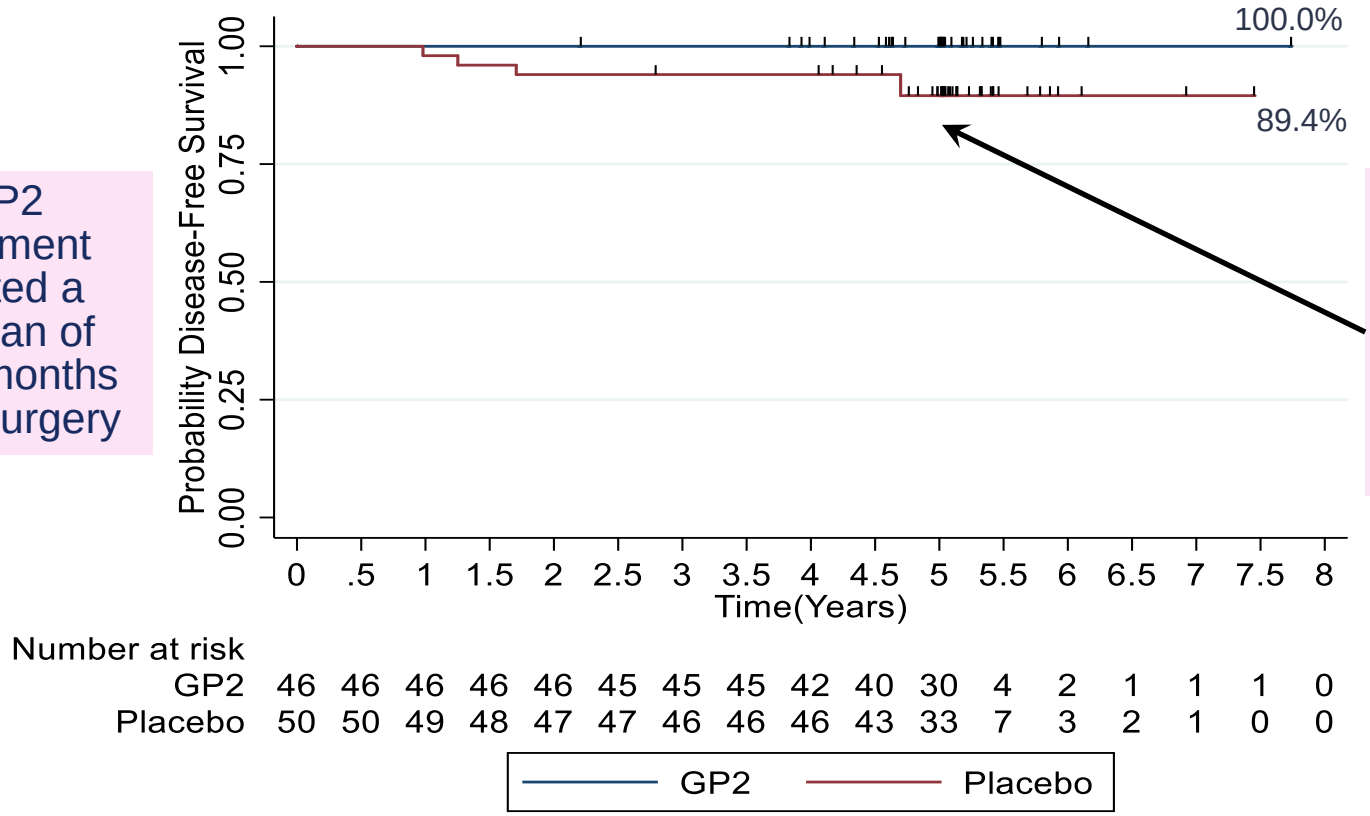
SABCS 2020 – 100% Disease Free Survival

Figure 1: HER2 3+ Patients Who Completed Primary Immunization Series Following Trastuzumab

GP2 treatment started a median of 17.1 months after surgery



Median 5 year follow-up after start of treatment & 6.4 years follow-up after surgery

After 5 years of follow-up, the Kaplan-Meier estimated 5-year DFS rate in the 46 HER2 3+ patients treated with GP2+GM-CSF, if the patient completed the PIS, was 100% versus 89.4% (95% CI:76.2, 95.5%) in the 50 placebo patients treated with GM-CSF (*p = 0.0338*).

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AACR 2021 – Immune Response Peaks at 6 Months

Dimer Binding Assay

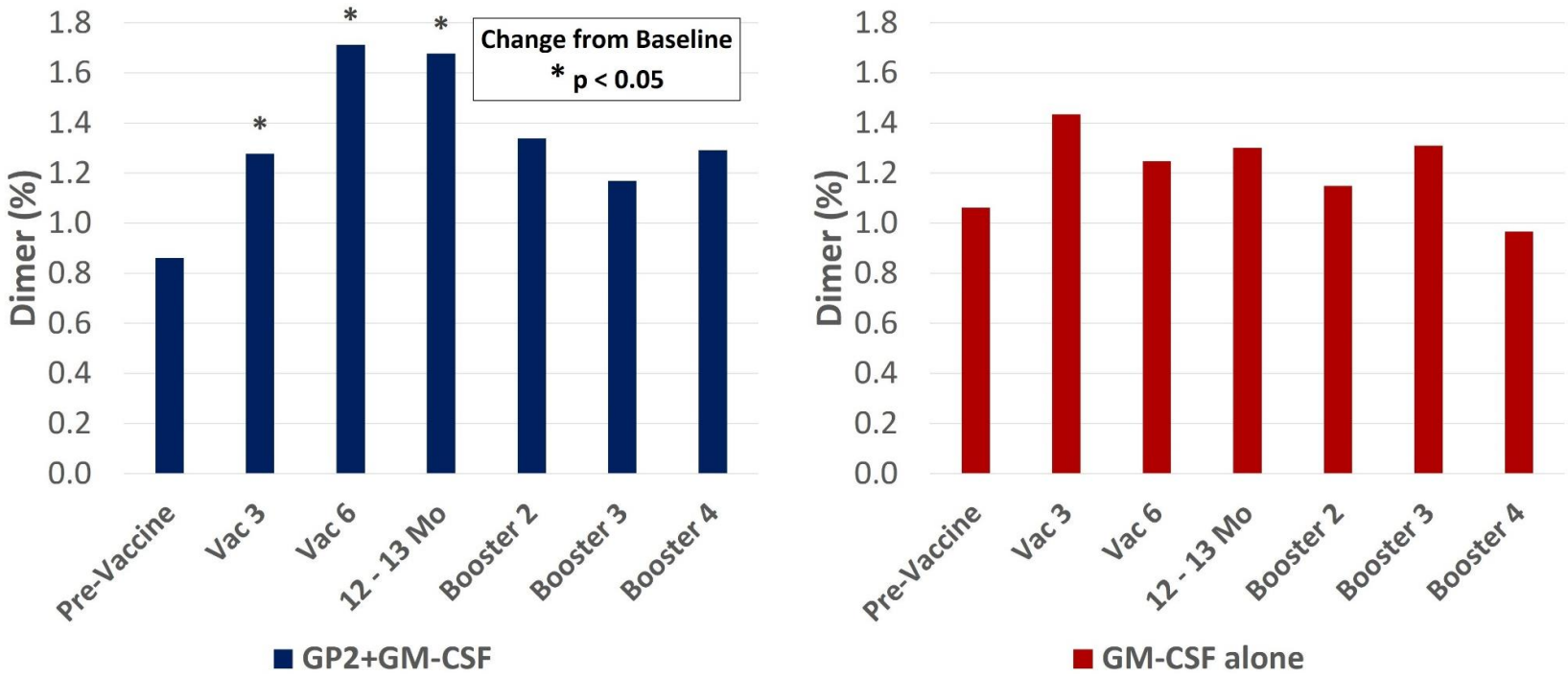
The Dimer Binding Assay detects the percentage of GP2 specific killer T cells that can kill recurring cancer cells. Ex vivo immune response was assessed over 2.5 years with blood draws at baseline, then after the 3rd and 6th immunizations in the Primary Immunization Series, and then after each booster. Immune responses were assessed by phenotypic clonal expansion assays in the majority of patients (n=113). GP2-specific CTLs were quantified in patients treated with GP2 using the Ig:A2 Dimer Assay and demonstrated an expansion over time, showing an increase over baseline after the 3rd immunization and remaining elevated for the entire course of follow-up.

DTH Skin Test

The DTH skin test measures the diameter of the skin immune response to GP2 in millimeters, 48-72 hours after intradermal injection of GP2 without GM-CSF. A DTH reaction was used to assess in vivo immune responses in patients (n=150). The DTH orthogonal mean of the skin wheal was measured 48-72 hours after injection using the sensitive ballpoint-pen method and is compared using a Wilcoxon Rank-Sum. For GP2 treated patients, there was a significant increase in DTH reactions after the PIS compared to baseline DTH reactions.

AACR 2021 – Immune Response Dimer Binding Assay

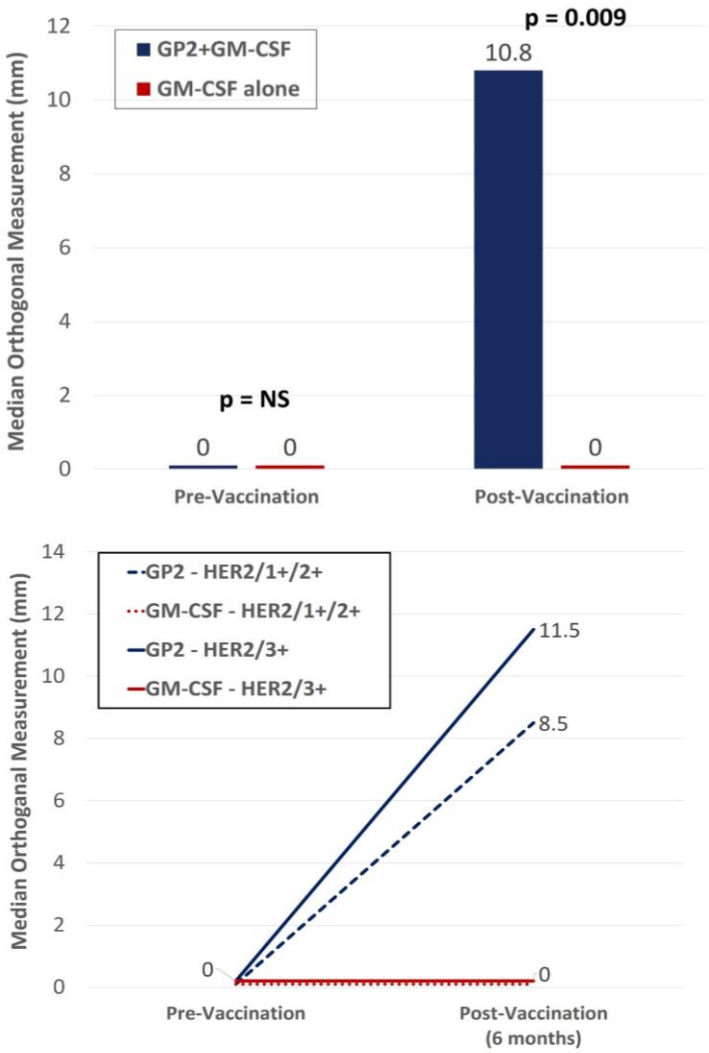
Figure 2: GP2-specific CTLs by Dimer Assay for HER2 3+



GP2 treated patients showed statistically significant dimer readings versus baseline (pre-vaccination) at 3, 6, and 12-13 months. GP2-specified CTLs were quantified using the Ig:A2 Dimer Assay. The assay was assessed over time and the results are presented in Figure 2 for HER2 3+ patients. Immune response in GP2-treated patients increased quickly during the 6 primary vaccinations (PIS) and remained statistically significantly above baseline for 6 months after the PIS ended. Some patients received booster vaccinations beginning at 12 months and the immune response was assessed one month after vaccination.

AACR 2021 – Immune DTH Skin Test

Figure 3: Delayed Type Hypersensitivity Skin Test (DTH)



After completion of the 6th immunization after 6 months, GP2 treated patients showed a robust immune response using the DTH skin test, while the placebo did not ($p = 0.009$). Within GP2 treated patients, the change from baseline after 6 months was a median of 4.8 mm (mean of 11.6 mm), which was a statistically significant increase over baseline ($p < 0.0001$). The change from baseline in DTH at 6 months was more robust in the GP2 treated patients. Those patients had an 11.6 mm mean increase in DTH after 6 months of exposure while patients treated with GM-CSF alone had a 5.2 mm mean increase ($p = 0.023$). This DTH data supports the Dimer Binding Assay data that shows a peak immune response after 6 months.

The DTH immune response for GP2 treated patients was similarly robust in HER2 3+ patients and HER2 1-2+ patients, independent of prior trastuzumab treatment and HER2 expression levels. Thus, GP2's robust immune response in the HER2 1-2+ population suggests the potential to apply GP2 immunotherapy to HER2 low to intermediate expressing breast cancers, as well as to other HER2 1-3+ expressing cancers.

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ASCO 2021 – Major 5 Year Data Set of GP2 Phase IIb Trial

Figure 1: Safety, Immune Response, & DFS in HER2 3+ Patients Who Completed Primary Immunization Series

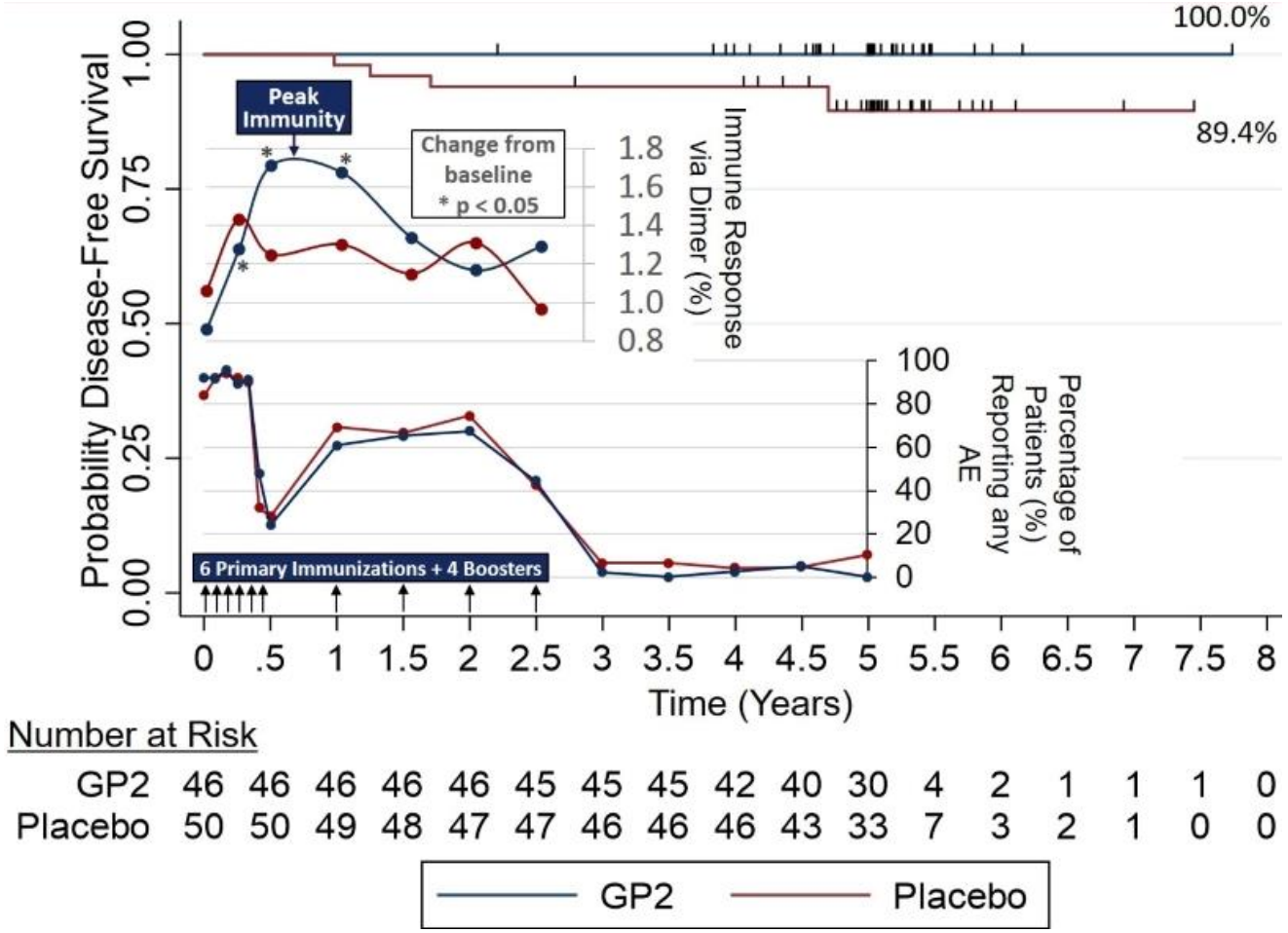

Figure 1 shows a time series of the GP2 immunotherapy injections, adverse events (AE), immune response, and 100% disease-free survival (0% recurrence rate) in HER2 positive breast cancer patients over median 5 years. This time series highlights that the 10 GP2 immunotherapy injections over the first 2.5 years (as depicted by the 10 arrows) created a potent immune response that peaked at 6 months. The immune response includes injection site and systemic reactions (types of adverse events) that also peaked at 6 months. These adverse events are a positive sign that the immune system responded to GP2 immunotherapy and prevented metastatic breast cancer recurrence. Adverse events were temporally associated with GP2 injections and declined after GP2 injections ended.

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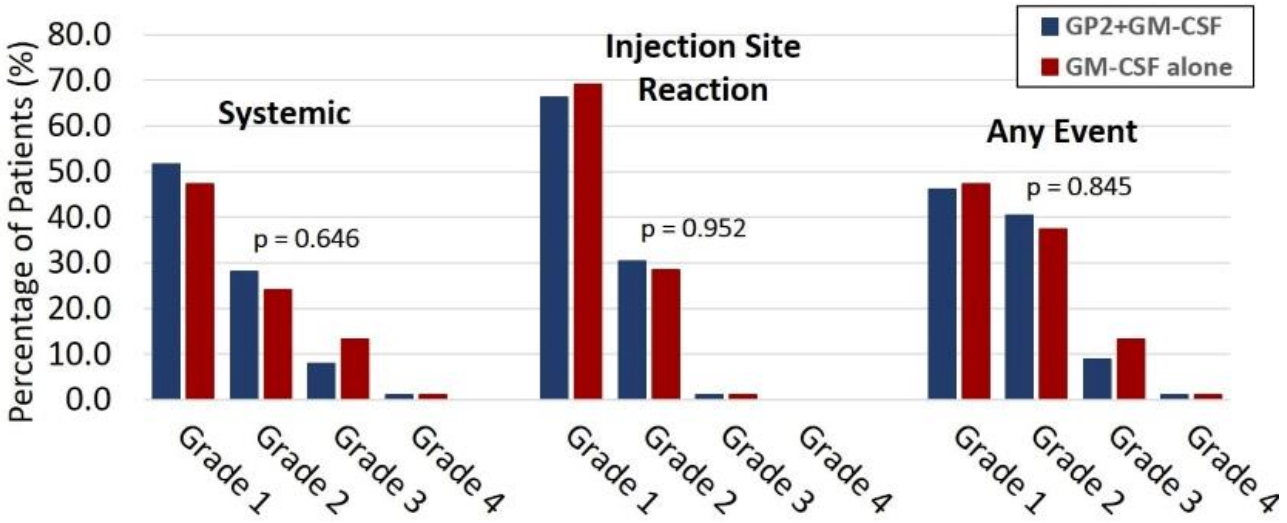
ASCO 2021 – Systemic & Injection Site Reactions

Figure 2: Incidence of Maximum Severity Grade Adverse Events



The maximal severity grade for any AE, systemic and injection site reaction, for each patient was identified. There was no difference between the two treatment arms, as presented in Figure 2. The majority of events were of grade 1, mild severity. Two patients reported grade 4 AEs deemed unrelated to study medication. One GP2+GM-CSF patient experienced grade 4 hypoglycemia and recovered. A GM-CSF only patient was diagnosed with renal cell carcinoma, a second primary diagnosis, which was classified as grade 4.

No serious adverse events considered related to study medication were reported

ASCO 2021 – Incidence of Adverse Events

Tables 1 & 2: Incidence of Adverse Events

Table 1: Incidence of First Occurrence of Most Frequent Adverse Events

	HER2 3+		HER2 1-2+		Total	
Adverse Event	GP2 (n = 51) N (%)	Placebo (n = 50) N (%)	GP2 (n = 38) N (%)	Placebo (n = 41) N (%)	GP2 (n = 89) N (%)	Placebo (n = 91) N (%)
Injection site reaction	50 (98.0)	50 (100)	37 (97.4)	40 (97.6)	87 (97.8)	90 (98.9)
Fatigue	36 (70.6)	30 (60.0)	26 (68.4)	25 (61.0)	62 (69.7)	55 (60.4)
Headache	23 (45.1)	26 (52.0)	1847.4)	19 (46.3)	41 (46.1)	45 (49.5)
Myalgia	19 (37.3)	16 (32.0)	13 (34.2)	10 (24.4)	32 (36.0)	26 (28.6)
Bone pain	12 (23.5)	17 (34.0)	12 (31.6)	10 (24.4)	24 (27.0)	27 (29.7)
Arthralgia	18 (35.3)	19 (38.0)	5 (13.2)	7 (17.1)	23 (25.8)	26 (28.6)
Malaise	14 (27.5)	11 (22.0)	7 (18.4)	9 (22.0)	21 (23.6)	20 (22.0)
Chills	12 (23.5)	14 (28.0)	7 (18.4)	6 (14.6)	19 (21.3)	20 (22.0)
Back pain	13 (25.5)	9 (18.0)	7 (18.4)	6 (14.6)	20 (22.5)	15 (16.5)
Nausea	9 (17.6)	15 (30.0)	5 (13.2)	6 (14.6)	14 (15.7)	21 (23.1)
Fever	12 (23.5)	13 (26.0)	5 (13.2)	4 (9.8)	17 (19.1)	17 (18.7)
Dizziness	6 (11.8)	4 (8.0)	2 (5.3)	3 (7.3)	8 (9.0)	7 (7.7)

Table 2: Incidence of First Occurrence of Injection Site Reactions

	HER2 3+		HER2 1-2+		Total	
Adverse Event	GP2 (n = 51) N (%)	Placebo (n = 50) N (%)	GP2 (n = 38) N (%)	Placebo (n = 41) N (%)	GP2 (n = 89) N (%)	Placebo (n = 91) N (%)
Erythema	50 (98.0)	50 (100.0)	37 (97.4)	39 (95.1)	87 (97.8)	89 (97.8)
Pruritus	50 (98.0)	46 (92.0)	37 (97.4)	38 (92.7)	87 (97.8)	84 (92.3)
Induration	50 (98.0)	40 (80.0)	37 (97.4)	36 (87.8)	87 (97.8)	76 (83.5)
Pain	9 (17.6)	5 (10.0)	6 (15.8)	5 (12.2)	15 (16.9)	10 (11.0)
Warm	3 (5.9)	5 (10.0)	2 (5.3)	0 (0.0)	5 (5.6)	5 (5.5)
Bruising	1 (2.0)	4 (8.0)	2 (5.3)	0 (0.0)	3 (3.4)	4 (4.4)
Urticaria	1 (2.0)	3 (6.0)	1 (2.6)	1 (2.4)	2 (2.2)	4 (4.4)
Rash	1 (2.0)	2 (4.0)	1 (2.6)	0 (0.0)	2 (2.2)	2 (2.2)
Blanching	2 (3.9)	1 (2.0)	0 (0.0)	0 (0.0)	2 (2.2)	1 (1.1)
Burning	1 (2.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (1.1)
Myalgia	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (1.1)	0 (0.0)
Tingling	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	0 (0.0)

The first occurrence of frequently reported AEs is tabulated in Table 1. The most common AE was injection site reaction. Almost every patient, in both the GP2+GM-CSF and GM-CSF only arms, reported injection site reactions.

The most frequent injection site reactions were erythema, pruritus and induration, as presented in Table 2. The incidence in AEs was similar across HER2 3+ and HER2 1-2+ patients.

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2021 SABCS Baseline GP2 Immune Response May Predict Faster & Earlier Recurrence

Figure 1: Time to Recurrence by Baseline DTH Response in Subgroup of Patients Experiencing Breast Cancer Recurrence

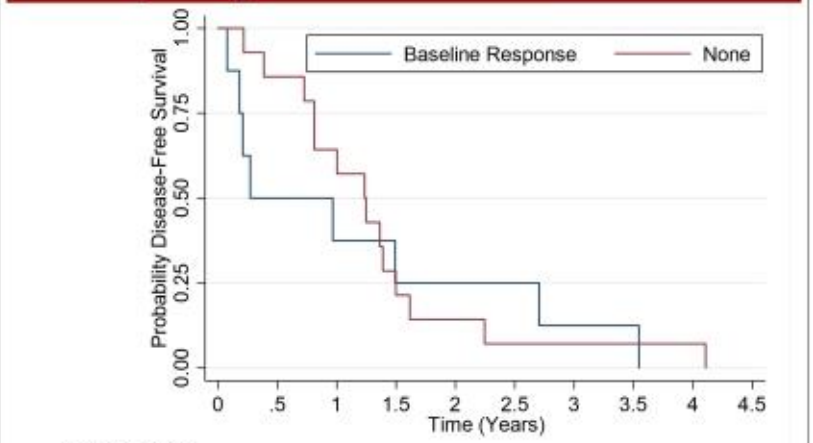
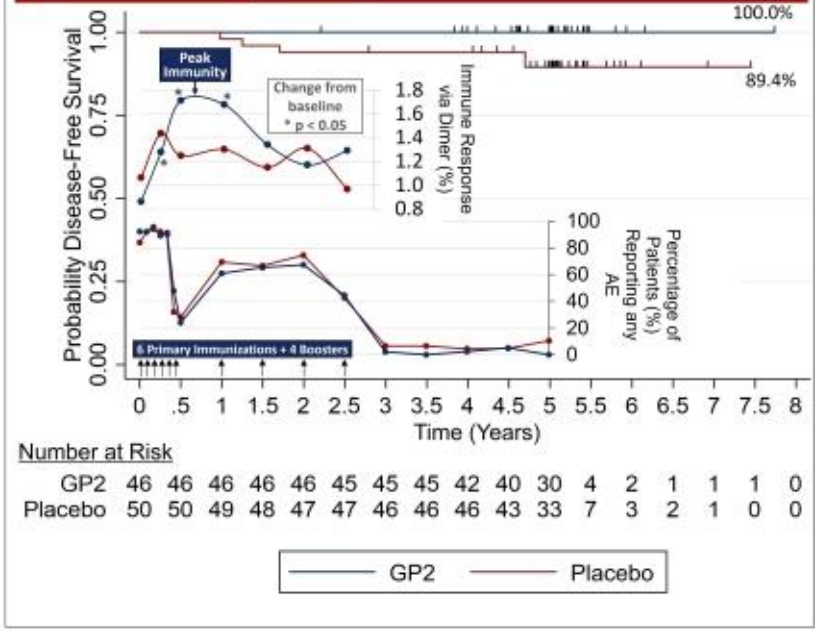


Figure 2: Safety, Immune Response, and Disease-free Survival in HER2 3+ Patients Who Completed PIS



- Identifying GP2 specific T cell immune response at baseline prior to treatment with GP2 has potential to predict breast cancer recurrence risk and timing of recurrence
- A positive baseline immune response to GP2 in 22.8% of 145 patients suggests an existing immune response to GP2 associated with residual disease, impending recurrence, or prior treatments
- DNA sequencing of relevant GP2 specific T cells at baseline and during GP2 treatment could lead to potential CAR-T cell drug candidates
- Data further validates 0% metastatic breast cancer recurrence mechanism and reaffirms that GP2 is a natural antigen that should be the target of peptide and T cell based platform technologies

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GP2 Planned Phase III Trial:

Strategy – Conservatively Reproduce Phase IIb Trial in Larger Population

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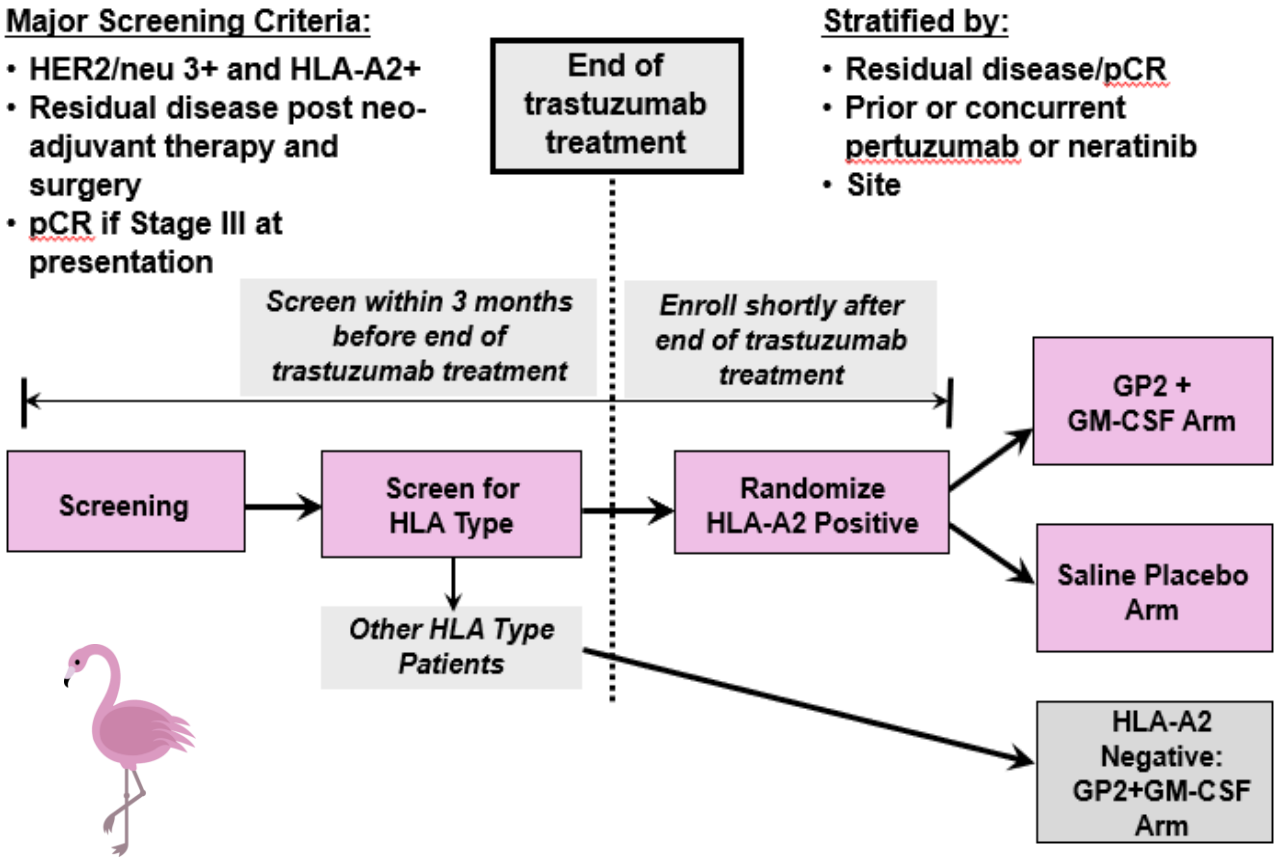
Flamingo-01 - Phase III Trial Has Commenced

- Phase III clinical trial, Flamingo-01, has officially started
- Multiple sites have begun the screening and enrolling process
- Flamingo-01 is evaluating the safety and efficacy of GLSI-100 (GP2 + GM-CSF) in HER2/neu positive breast cancer patients who had residual disease or high-risk pathologic complete response at surgery
- What is next – transition into pre-commercialization activities:
  - Working with the FDA in preparation for a BLA submission and commercial launch
  - Implementing a global strategy for launching GP2 in international markets outside the US and Europe
  - Initiating large scale manufacturing, packaging, and marketing
- Additional activities/milestones:
  - Phase III clinical trial progress and open label data will be presented at major conferences
  - Licensing discussions may accelerate as the interim analysis approaches
  - Other assets may be developed by acquisition or internal research, including T cell therapies that may be discovered in the Phase III trial by studying GP2's robust immunogenicity
  - Additional patents for GP2 based on the Phase III trial findings, manufacturing, and pharmacy procedures are planned to be filed to extend patent life

Flamingo-01 - Phase III Trial Schema & Interim Analysis

Phase III Trial Schema



Interim Analysis Design

Preliminary Sizing of Trial:

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..

- GLSI-100 (GP2 + GM-CSF), Placebo (Saline)
- Enroll in 1.5 years or longer
- Compare iDFS of GP2-treated versus placebo using standard of care

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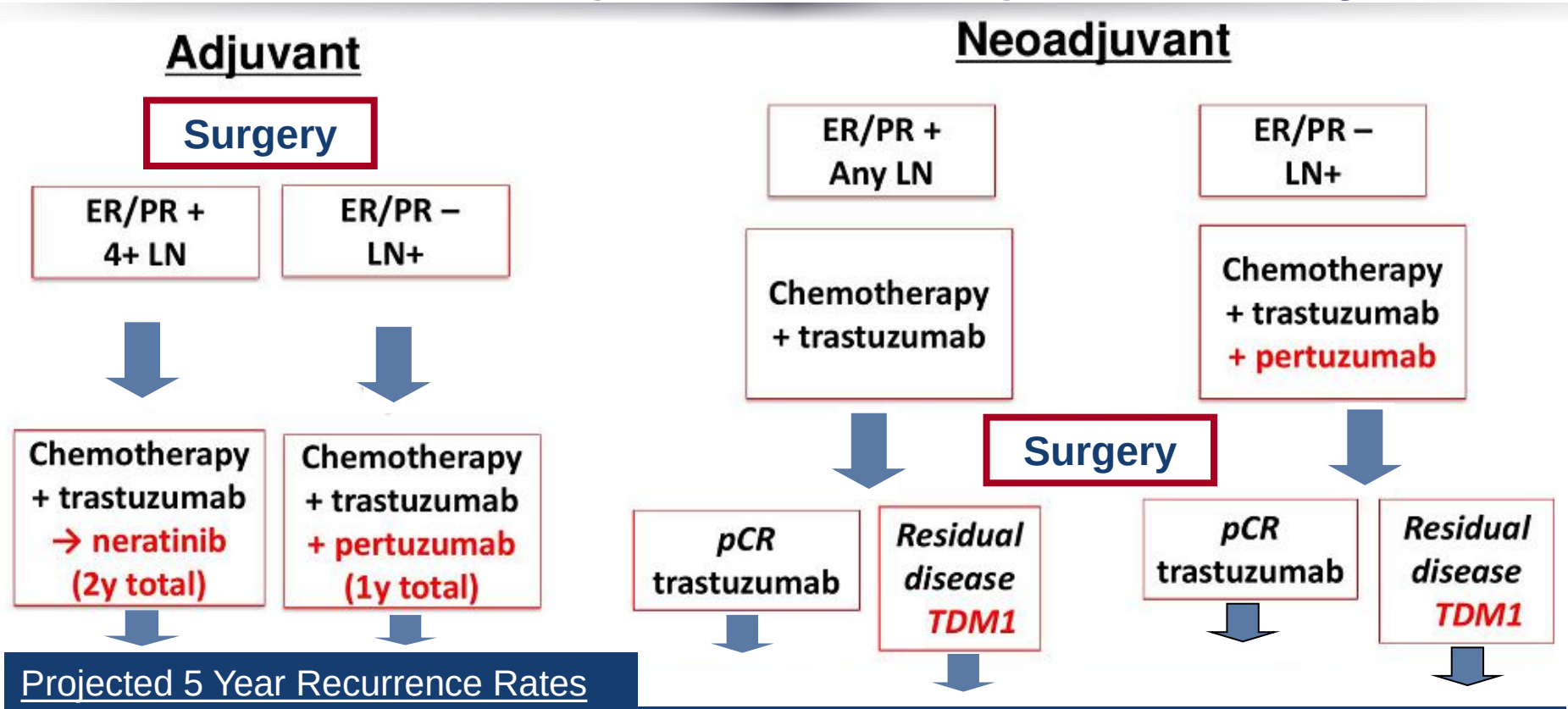
GP2 May Address Unmet Need in Both HER2/neu 3+ Adjuvant & Neoadjuvant Settings



Conclusion: GP2 should eventually be pursued in both settings for all HER2 positive patients

Target Population for Phase III Trial: Residual Disease & High Risk pCR

Annual recurrence rate = 3.0-3.4%

Annual recurrence rate design for Phase III trial = 2.4%

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Manufacturing / Regulatory / IP

- GP2 manufactured by straightforward amino acid chemistry
  - Manufactured by FDA-approved commercial facility with multiple back-up facilities
  - Detailed CMC plan reviewed by FDA
  - Commercial scale manufacturing commenced
  - 3 clinical lots followed by 3 commercial lots
  - GM-CSF is commercially available, along with Saline/WFI, which will all be sold independently
- Phase III trial protocol reviewed by FDA
- Discussing potency assay / HLA companion diagnostic
- GP2 registered as biologic with CBER – 12 years exclusivity in US
- GP2 issued patents provide protection through 2032 in the major markets (US, EU, Canada, Australia, & Japan), including ongoing prosecution in emerging markets - patent term extensions possible
- New patent applications

GP2 Commercial Opportunity

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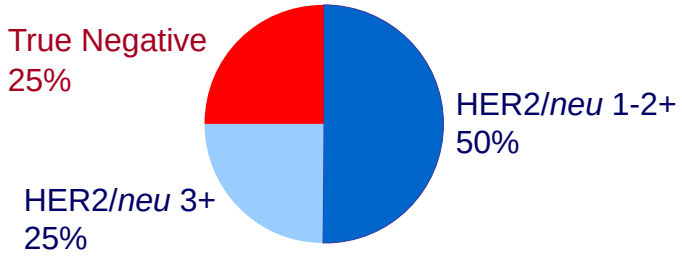
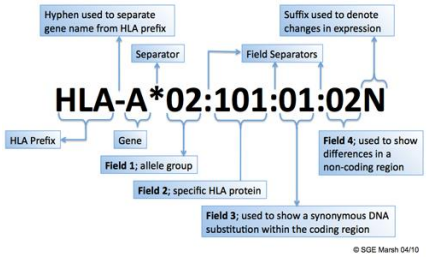
Potential Indications of GP2 & Herceptin in Various Populations in Neoadjuvant Setting

- HER2/*neu* 3+ protein over-expression (25%) & 1-2+ expression (50%)
  - All breast cancer patients are tested for HER2/*neu* expression by immunohistochemistry (IHC) or fluoresecence in situ hybridisation (FISH)



- Node Positive (60%) & High Risk Node Negative (40%)
  - Node positive – cancer has spread to lymph nodes
  - High risk node negative – no cancer in lymph nodes but at high risk for recurrence
  - The more lymph node involvement the more aggressive the cancer
- Hormone Receptor Positive (60%) & Hormone Receptor Negative (40%)
- HLA Type: HLA-A2 (40-50%) & HLA-A3,A24 (30%)
  - Human leukocyte antigen (HLA) presents peptide from inside cancer cell to killer T-cells
  - HLA also presents injected peptide to create killer T-cells following intradermal injection



- 30% of 282k new US breast cancer patients per year could lead to up to 85k new patients per year for GP2
- 30% of 3.8m long term US breast cancer survivors could be candidates for GP2

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Commercial Opportunity for GP2 in Breast Cancer

- **1 in 8 U.S. women (12.8%) will develop invasive breast cancer over her lifetime, with 282k new breast cancer patients per year in 2021**
- **An estimated 43,600 female breast cancer deaths will occur in the US in 2021**
- **GP2's target market is 6-30% of available breast cancer market or up to 2.4x that of Herceptin in adjuvant setting**
- **GP2 could be a long term treatment that treats survivors (3.8m as of 2021)**
- **Herceptin/Perjeta/Nerlynx/Kadcyla pricing from $75k - $125k per patient per year**
- **11 doses over 3 years in initial indication**

	Herceptin	GP2
US Market Potential (Size = 3.8m current breast cancer survivors and 282k new patients per year)		
HER2/*neu* Expressors (1-3+)	25% (3+)	25-75% (1-3+)
HLA Type	100%	50-80% (2/3/24/26)
Node Positive (NP) or High Risk Node Negative (HRNN)	50%	50%
Target Market Potential	12.5%	6.25 - 30%
Theoretical New Patients per Year	35,250	17,625 – 84,600
Adjuvant Patients Treated per Year (est. from sales)	27,000 – 40,000	
Estimated Adjuvant Setting US Revenue ($ billions)	$2-3	
Estimated Price (first year)	$74,500	TBD (6 primary + 1 booster)
Estimated Price (booster)	Not Approved	TBD (4 boosters over 2 years)
Estimated 2017 Global Revenue ($ billions)	$7	
Adjuvant Setting	$2-3	
Metastatic Breast Cancer	$4-5	

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GP2 Acts Synergistically with Herceptin, Perjeta, Nerlynx, & the Newest Entrants Kadcyla and Enhertu

- Genentech's Herceptin (trastuzumab) in Y1 post-surgery
  - Reduces recurrence rates from 25% to 12% by Y4 post-surgery
    - Node Positive and High Risk Node Negative
    - Side Effects: Cardiotoxic, 1 year treatment only

Herceptin ADC 4:1

- Genentech's Perjeta (pertuzumab) in Y1 with Herceptin
  - Reduces recurrence rates in Node Positive from 13% to 10% & in Hormone Receptor Negative from 11% to 9% by Y4 post-surgery
    - Side Effects: Adverse reactions (>30%) - diarrhea, nausea, alopecia, fatigue, peripheral neuropathy and vomiting.

Approved on Y3 Post-Surgery Data

PERJETA® pertuzumab for injection

nerlynx® (neratinib) tablets

- Puma's Nerlynx (neratinib) in Y2 post-Herceptin
  - Reduces recurrence rates overall from 12% to 10% & in Hormone Receptor Positive from 13% to 9% by Y6 post-surgery
    - Side Effects: 95% all-grade diarrhea & 40% grade 3/4 (reduced 20% with loperamide prophylaxis), nausea (43%), fatigue (27%), vomiting (26%), & abdominal pain (24%).

ENHERTU® fam-trastuzumab deruxtecan-nxki 20 mg/mL INJECTION FOR INTRAVENOUS USE

Herceptin ADC 8:1

Substantial Unmet Need: GP2 & GM-CSF starting in Y2 act synergistically with Herceptin to prevent cancer recurrences, if fully immunized, reducing recurrence rates from **11% to 0% at median 5 years follow-up, minimal to no side effects, & no SAEs**

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Potential Commercial Opportunities / Additional Indications for GP2: HER2/*neu* Expressed in Multiple Cancers

Figure 3. Leading Sites of New Cancer Cases and Deaths – 2021 Estimates

Estimated New Cases

Male			Female		
Prostate	248,530	26%	Breast	281,550	30%
Lung & bronchus	119,100	12%	Lung & bronchus	116,660	13%
Colon & rectum	79,520	8%	Colon & rectum	69,980	8%
Urinary bladder	64,280	7%	Uterine corpus	66,570	7%
Melanoma of the skin	62,260	6%	Melanoma of the skin	43,850	5%
Kidney & renal pelvis	48,780	5%	Non-Hodgkin lymphoma	35,930	4%
Non-Hodgkin lymphoma	45,630	5%	Thyroid	32,130	3%
Oral cavity & pharynx	38,800	4%	Pancreas	28,480	3%
Leukemia	35,530	4%	Kidney & renal pelvis	27,300	3%
Pancreas	31,950	3%	Leukemia	25,560	3%
All sites	**970,250**		**All sites**	**927,910**	

Estimated Deaths

Male			Female		
Lung & bronchus	69,410	22%	Lung & bronchus	62,470	22%
Prostate	34,130	11%	Breast	43,600	15%
Colon & rectum	28,520	9%	Colon & rectum	24,460	8%
Pancreas	25,270	8%	Pancreas	22,950	8%
Liver & intrahepatic bile duct	20,300	6%	Ovary	13,770	5%
Leukemia	13,900	4%	Uterine corpus	12,940	4%
Esophagus	12,410	4%	Liver & intrahepatic bile duct	9,930	3%
Urinary bladder	12,260	4%	Leukemia	9,760	3%
Non-Hodgkin lymphoma	12,170	4%	Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,500	3%	Brain & other nervous system	8,100	3%
All sites	**319,420**		**All sites**	**289,150**	

Estimates are rounded to the nearest 10, and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Estimates do not include Puerto Rico or other US territories. Ranking is based on modeled projections and may differ from the most recent observed data.

Denotes cancers where HER2/*neu* over expression has been reported

Veteran Management Team / Board

- David McWilliams, MBA – Chairman, Board
  - 40 years of start-up / CEO experience
  - CEO of 2 private and 3 public biotech companies
- Snehal Patel, MS, MBA – CEO, Board
  - 30 years of biopharma / Wall Street experience
  - Large pharma operations / management experience
- Joe Daugherty, M.D. – CMO, Board
  - 35 years of biopharma experience
  - Assisted over 20 public and private companies
- Jaye Thompson, Ph.D. – VP Clinical & Regulatory
  - 30 years of active involvement in over 200 clinical trials for drugs, biologics and devices
  - Founder of multiple CROs
- Christine Fischette, Ph.D. – VP Business Development
  - 30 years of big pharma R&D & commercialization
  - Business development / multiple licensing transactions
- Eric Rothe – Board & Founder of GLSI
- Ken Hallock – Board & Major Investor

Abbott
McKinsey&Company
ENCYSIVE PHARMACEUTICALS
OPEXA THERAPEUTICS
BAYER Bayer
JPMorganChase
eleos
Massachusetts Institute of Technology
CONAGRA BRANDS
DUPONT
inVentiv Health
Repros THERAPEUTICS INC.
NOVARTIS
Roche
Pfizer
THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Making Cancer History®
General Electric
INTROGEN Therapeutics, Inc.

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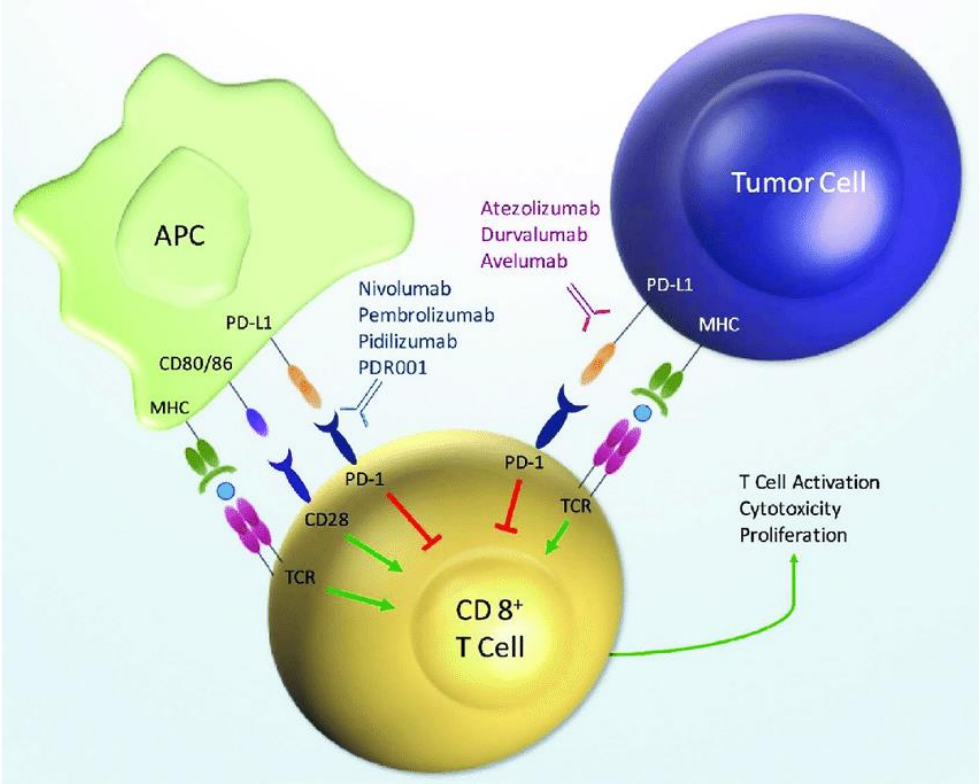
GLSI Strategy is to Conduct Additional GP2 Trials

Greenwich's current strategy is as follows:

- **Reproduce** Phase IIb trial in Phase III trial in HER2 positive patients only – no material changes to treatment regimen, upgrade immune response assays, expand to multiple HLA types
- **Optimize** GP2 treatment by starting treatment in neoadjuvant setting in another Phase II/III trial and utilize immune response data, if possible, to "optimize" timing of inoculations
- **Expand** to HER2 low breast cancer and other HER2 expressing cancers using optimized treatment methods and add checkpoint inhibitors

Add Checkpoint Inhibitors



ROE of developing GP2 could be high!

GP2 Conclusions: A Breakthrough Targeted Immunotherapy for Prevention of HER2/*neu* Cancer

- Flamingo-01 - Phase III Trial with Interim Analysis: 9 amino acid HER2/*neu* peptide + GM-CSF immunotherapy for breast cancer in adjuvant/neoadjuvant setting (post-surgery) in HER2/*neu* 3+, HLA-A2 patients in Y2 following Herceptin or Kadcyla, led by Baylor & consortium of prominent cancer centers
- Conservative design of Phase III trial to reproduce Phase IIb results
- Phase IIb Trial Results: Randomized, multi-center (16 centers), placebo-controlled, **0% recurrences over median 5 years follow-up**, if fully immunized, versus 11% placebo recurrence rate in 96 patients (*p = 0.0338*), peak immunity after 6 months, minimal to no side effects, no SAEs attributable to GP2, led by MD Anderson Cancer Center
- Potential Opportunities to Expand Market:
  - HER2/*neu* 1-2+ patients with Herceptin - increase market from 25% to 75%
  - ✓ Other HLA types – increase from 40-50% up to 80% of all patients
  - Combination with CD4/CD8 peptides and checkpoints
  - Other HER2/*neu* cancers
- NASDAQ Ticker “GLSI”: Raised $36.5m since IPO

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NASDAQ: GLSI

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