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Planned GLSI-100 (GP2 + GM-CSF) Phase III Clinical Trial, FLAMINGO-01

A Breakthrough Targeted Immunotherapy to Prevent Breast Cancer Recurrences

NASDAQ: **GLSI**

Snehal Patel, CEO

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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 HER2/*neu* positive patients following neoadjuvant, surgery, & adjuvant Herceptin or Kadcyla, led by Baylor & consortium of prominent networks - up to 180 sites in US & EU

- Conservative design of Phase III trial to reproduce Phase IIb results
- Phase IIb Trial Results: Randomized, multi-center (16 centers), placebo-controlled, substantial reduction in recurrence rate, 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* low patients with Herceptin - increase market from 25% to 75%
  - ✓ Other HLA types – increase from 40-50% up to 80-100% of all patients
  - Combination with CD4/CD8 peptides and checkpoints
  - Other HER2/*neu* cancers
- NASDAQ Ticker “GLSI”: Raised $60m since IPO

Recently granted Fast Track designation by FDA

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First Year Share Price Performance After Presenting Key Phase IIb Data in 2020/2021

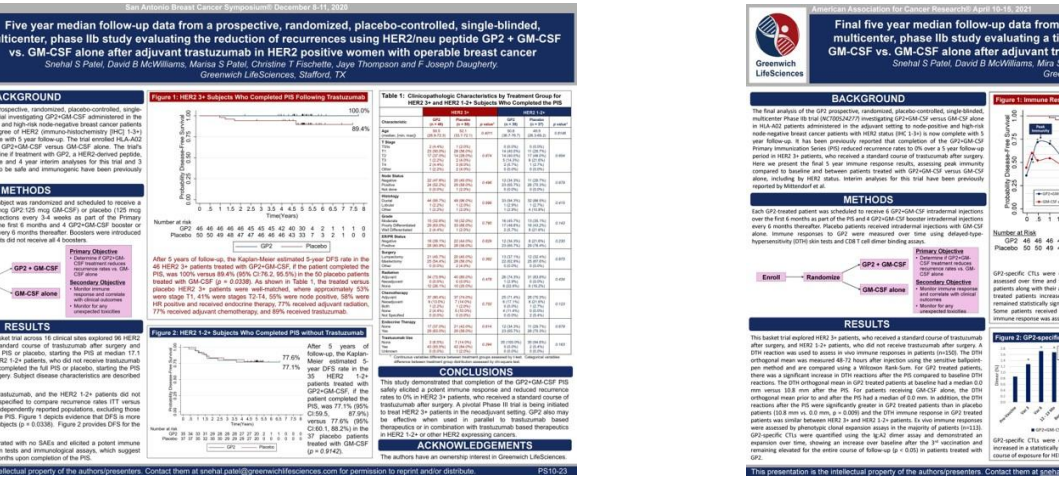
- Raised approximately $36.5M from IPO & Follow-on in 2020
- Peak share prices and trading volume driven by data publications
- 30x or 2,940% return from intraday high on 12/9/20, possibly highest intraday return for a non-penny stock from prior day close
- Added to Russell 2000 twice: 2021 and 2024
- Management & Directors ownership (tightly held): 75-85%
- Low float - Locked up from IPO in Sept 2020 through Jan 2027 at BOD discretion



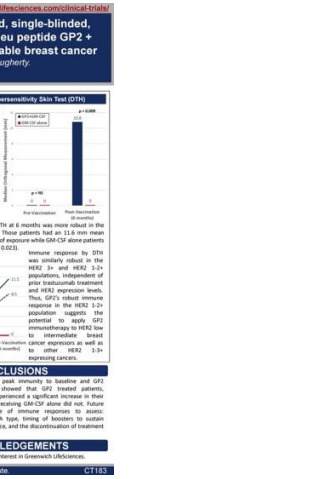
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2020-2021 - Four Posters Highlighting Efficacy, Mechanism of Action, Safety, & Prognostic Factors

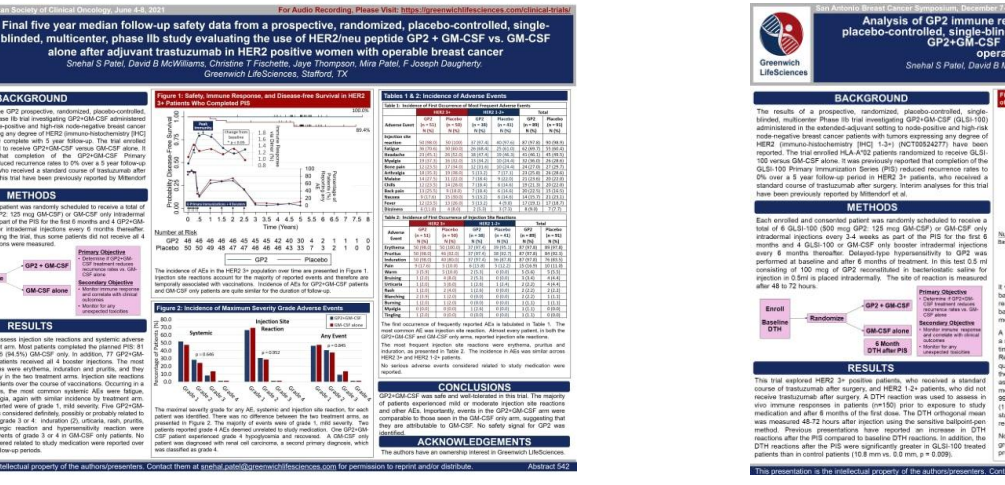
2020 San Antonio Breast Cancer Symposium (SABCS)
0% Recurrences Over 5 Years in Phase IIb Trial



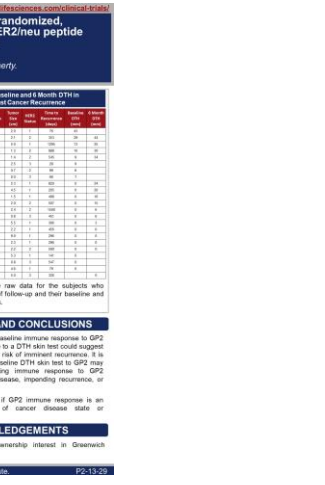
2021 American Association for Cancer Research (AACR)
Immune Response Supports Mechanism of Action



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



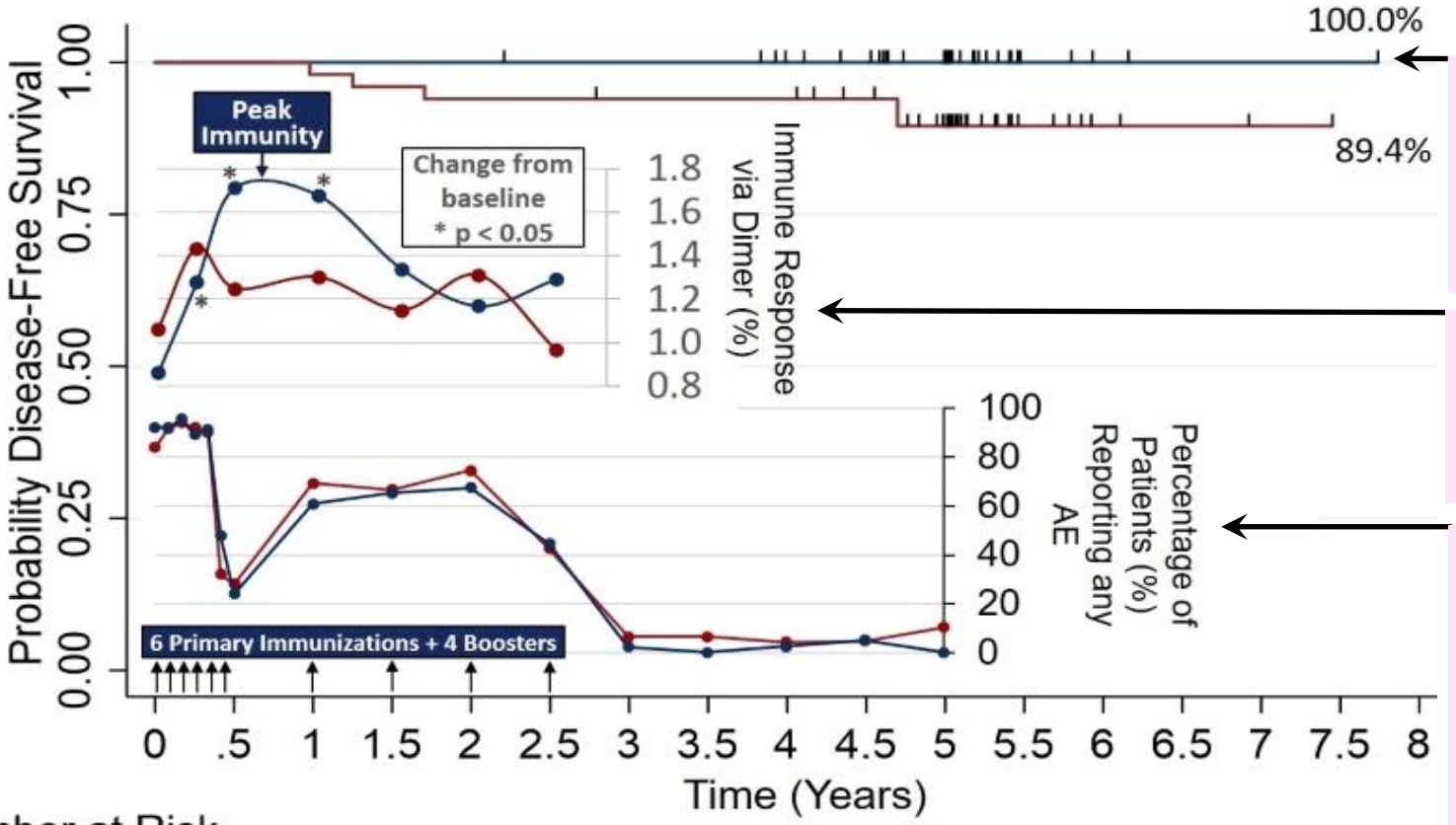
2021 SABCS Baseline GP2 Immune Response
May Predict Faster & Earlier Recurrence



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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)



Number at Risk

GP2	46	46	46	46	46	45	45	45	42	40	30	4	2	1	1	1	0
Placebo	50	50	49	48	47	47	46	46	46	43	33	7	3	2	1	0	0

GP2 — Placebo

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

Peak Immunity After 6 Months & PIS

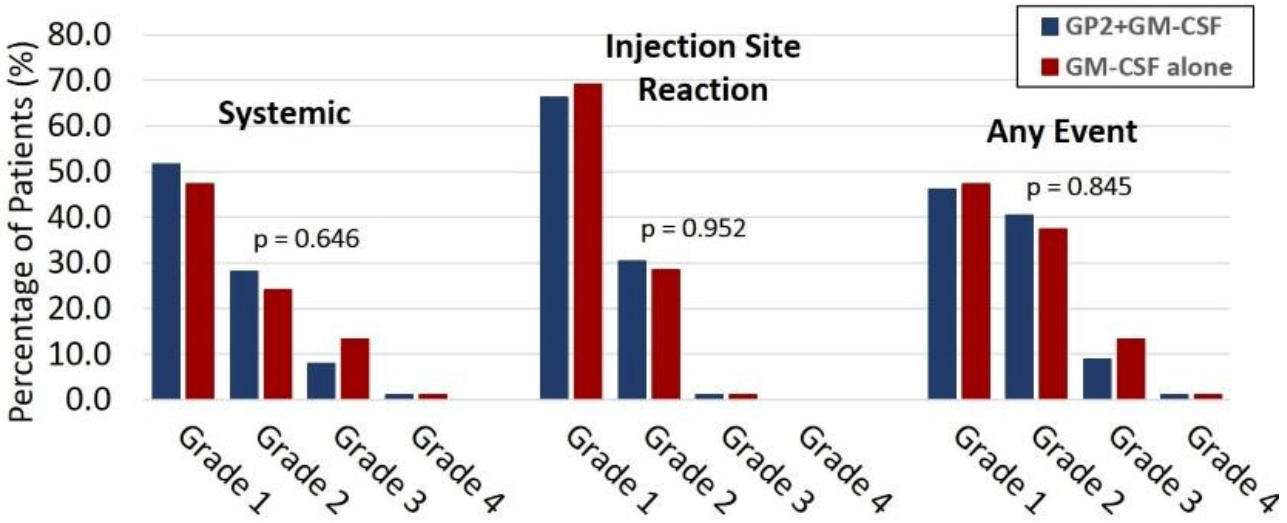
Injection Site & Systemic Adverse Events (AE) are Positive Sign of Immune Response – No SAEs attributable to GP2 treatment

**Results subject to final Clinical Trial Study Report being prepared for filing of BLA per 10K, ending 12/31/23, & per Phase IIb trial tab of Company website.

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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

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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

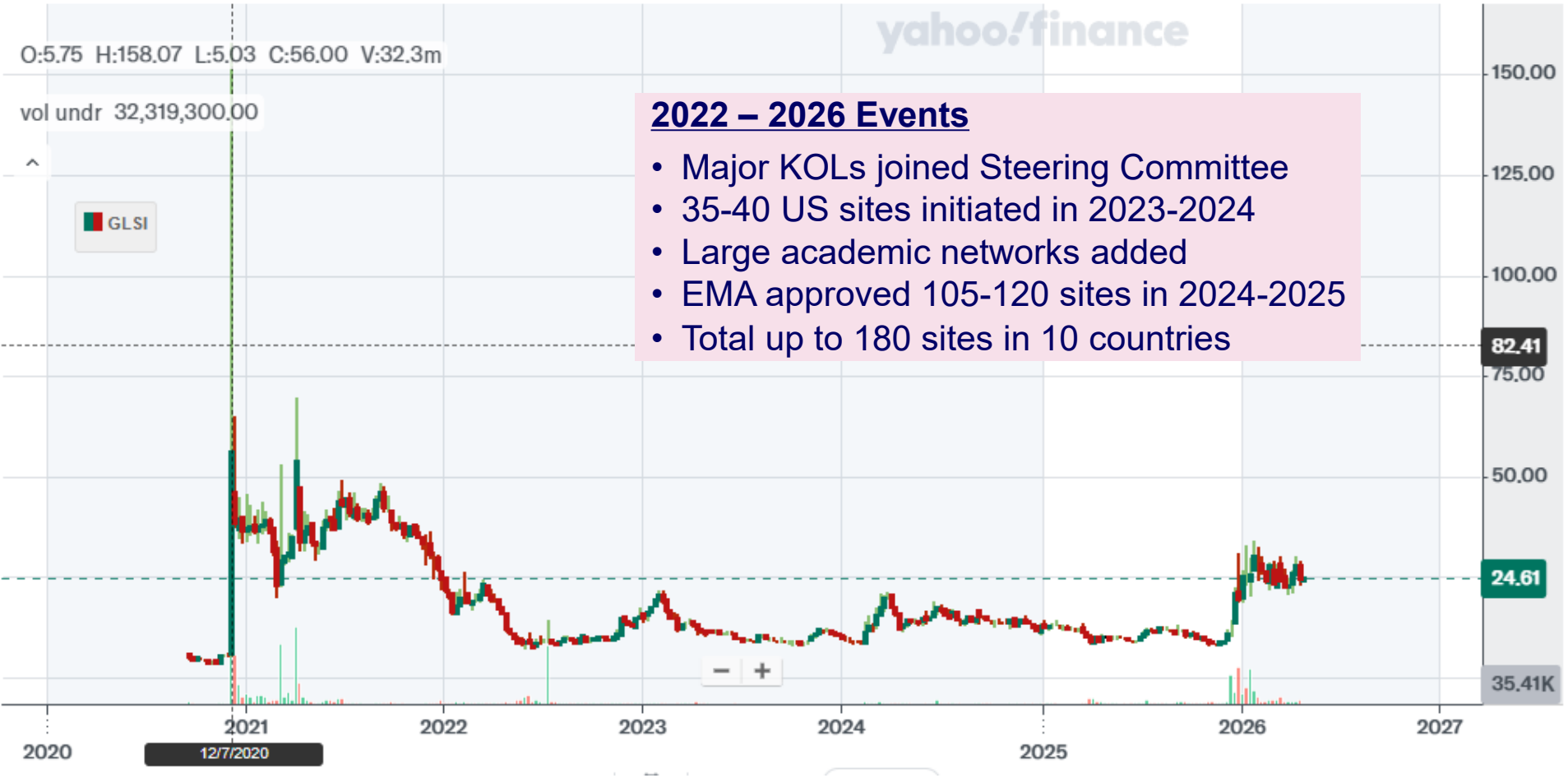
	HER2 3+		HER2 1-2+		Total	
Adverse Event	GP2 (n = 51) N (%)	Placebo (n = 50) N (%)	GP2 (n = 38) N (%)	Placebo (n = 41) N (%)	GP2 (n = 89) N (%)	Placebo (n = 91) N (%)
Erythema	50 (98.0)	50 (100.0)	37 (97.4)	39 (95.1)	87 (97.8)	89 (97.8)
Pruritus	50 (98.0)	46 (92.0)	37 (97.4)	38 (92.7)	87 (97.8)	84 (92.3)
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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6 Year Performance Since IPO – Planning & Initiation of Phase III Trial in up to 180 sites in 10 Countries



2022 – 2026 Events

- Major KOLs joined Steering Committee
- 35-40 US sites initiated in 2023-2024
- Large academic networks added
- EMA approved 105-120 sites in 2024-2025
- Total up to 180 sites in 10 countries

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Flamingo-01 Steering Committee

The Steering Committee is comprised of the following members :

- Dr. Mothaffar F. Rimawi – Professor of Medicine at the Baylor College of Medicine
- Dr. Francois-Clement Bidard – Professor of Medical Oncology, UVSQ/Paris Saclay University, Head of Breast Cancer Group, Institut Curie (Unicancer)
- Dr. William J. Gradishar – Professor of Medicine at the Feinberg School of Medicine at Northwestern University
- Dr. Sibylle Loibl – Professor (apl) Goethe University Frankfurt/M, Clinical Consultant Centre for Haematology and Oncology/Bethanien Frankfurt/M (GBG)
- Dr. Miguel Martin – Professor of Medicine, Head, Medical Oncology Service, Gregorio Marañón General University Hospital, Complutense University, Madrid, GEICAM
- Dr. Joyce A. O'Shaughnessy – Celebrating Women Chair in Breast Cancer, Baylor University Medical Center & Chair, Breast Cancer Program, US Oncology/Sarah Cannon
- Dr. Hope S. Rugo – Professor, Department of Medical Oncology & Therapeutics Research, City of Hope Comprehensive Cancer Center, Professor Emeritus, UCSF
- Dr. Laura M. Spring – Assistant Professor, Medicine, Harvard Medical School, Attending Physician, Medical Oncology, Massachusetts General Hospital
- Dr. Cesar A. Santa-Maria – Associate Professor of Oncology, Breast and Gynecological Malignancies Group, Director of Breast Cancer Trials, Johns Hopkins SKCCC

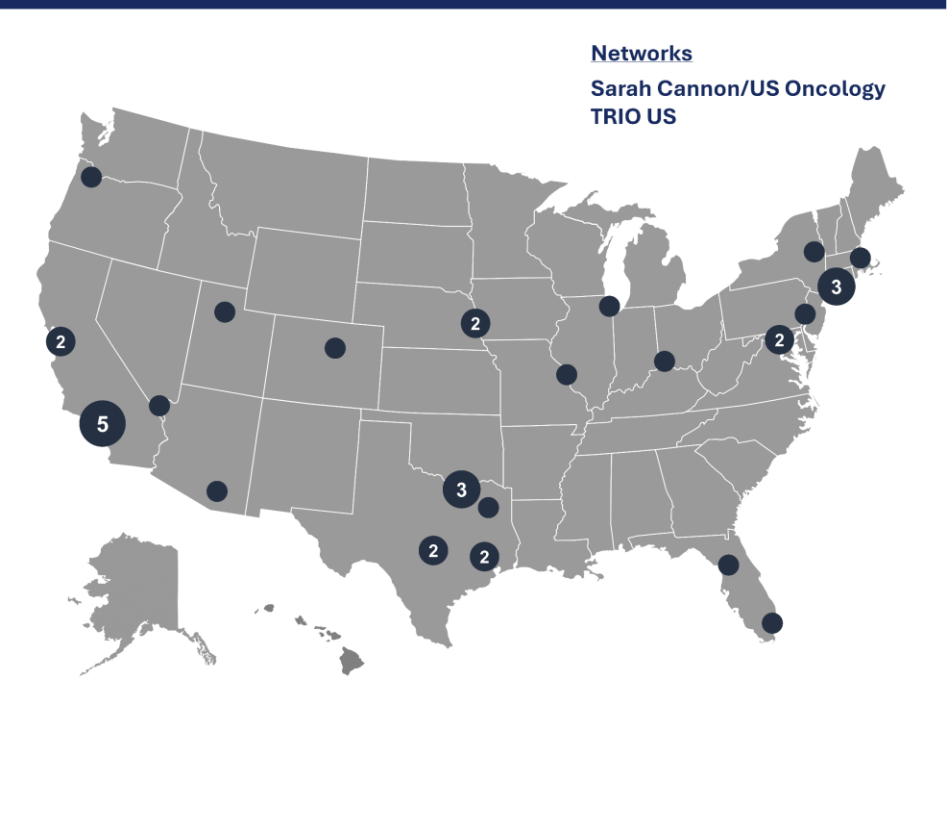
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Flamingo-01 Clinical Site Map – Up to 180 sites in US/EU

Participating networks: USOncology/Sarah Cannon, TRIO-US, GEICAM (Spain), Unicancer (France), GBG (Germany), GIM (Italy)

Potential additions: Canada, United Kingdom

US Sites



EU Sites



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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 is approved for use in patients with residual disease, who do not achieve a pCR, as determined 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 with minimal to no side effects & no SAEs.

In the initial GP2 indication in the US & EU, ~88k new patients could be treated per year, saving up to 7,000 to 10,000 lives per year.

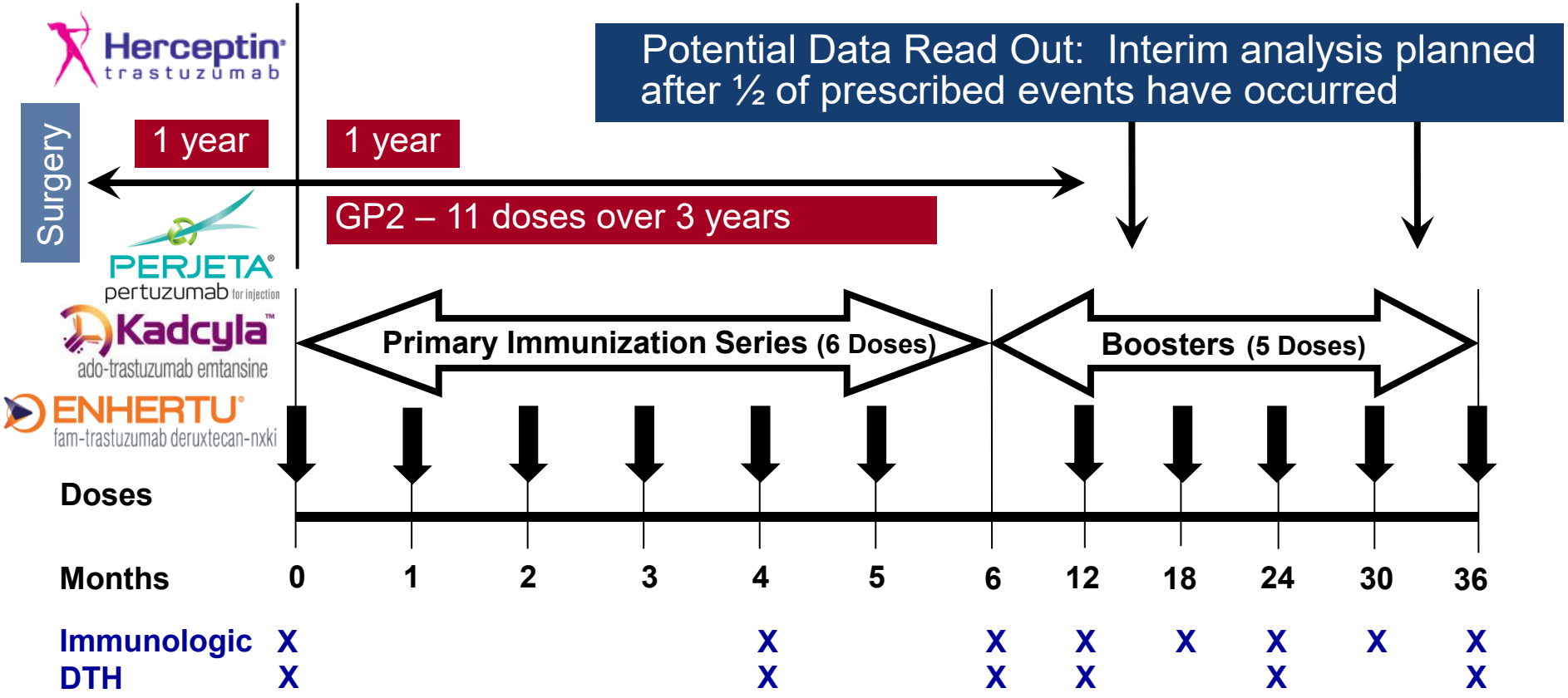
(12.5% * 700k new pts = 88k pts/yr for all HLAs)



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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

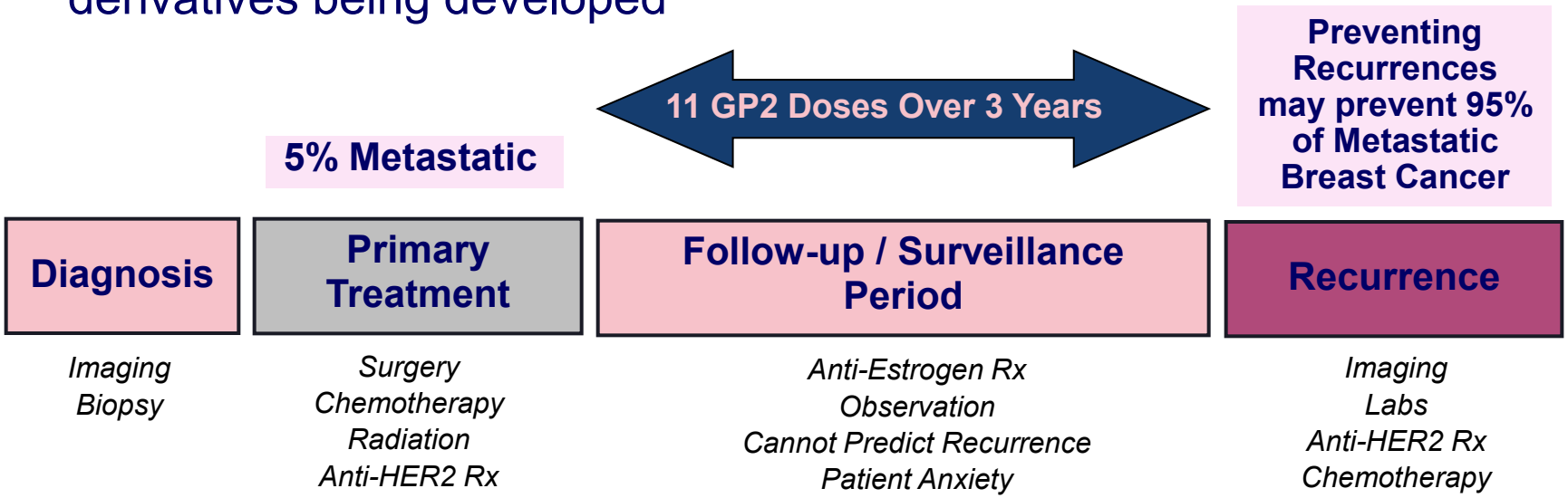


- Study allows prior use of pertuzumab, trastuzumab, and ado-trastuzumab emtansine and concurrent neratinib
- Final DTH/immunologic assays at 48 months and at time of recurrence

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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

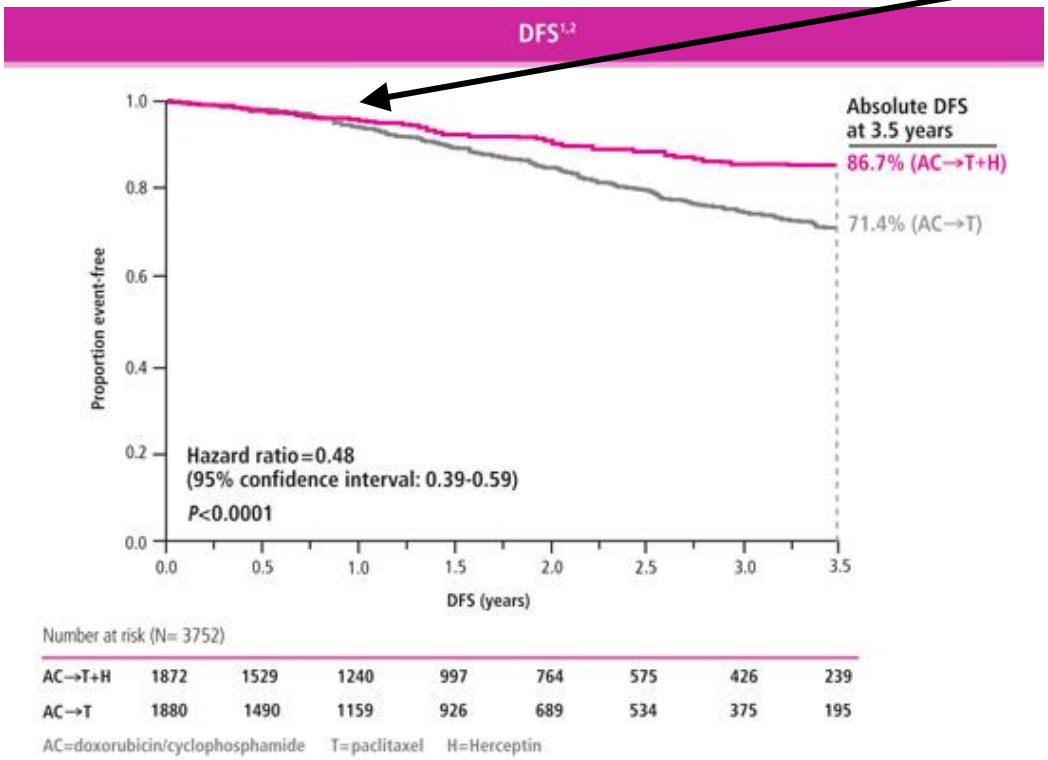


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Synergy with Herceptin Alone **

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

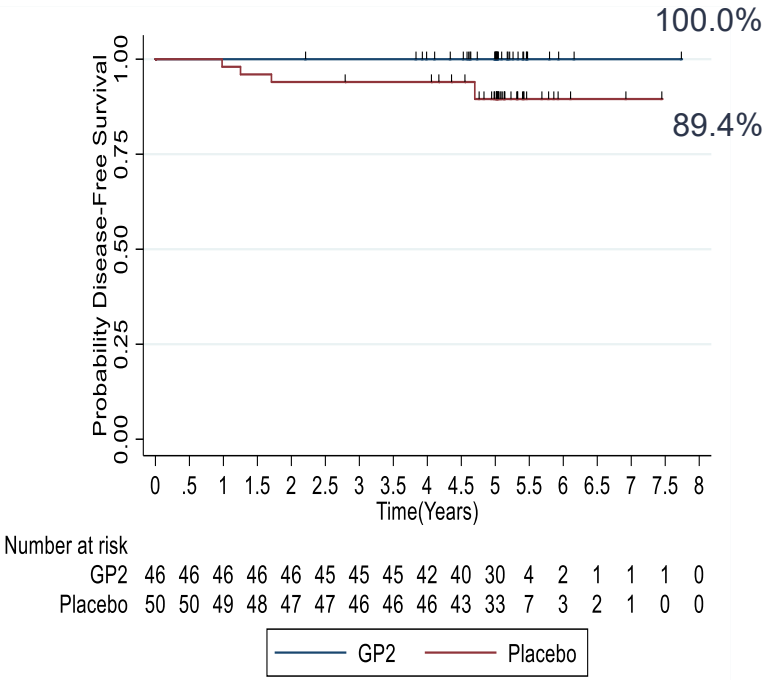
Herceptin Approved for Adjuvant Treatment of HER2/*neu* 3+ Breast Cancer



Joint Analysis Trial

*DFS – Disease Free Survival

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



ROW strategy: GP2 could eventually be developed with only trastuzumab biosimilar

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GP2 Clinical Data:

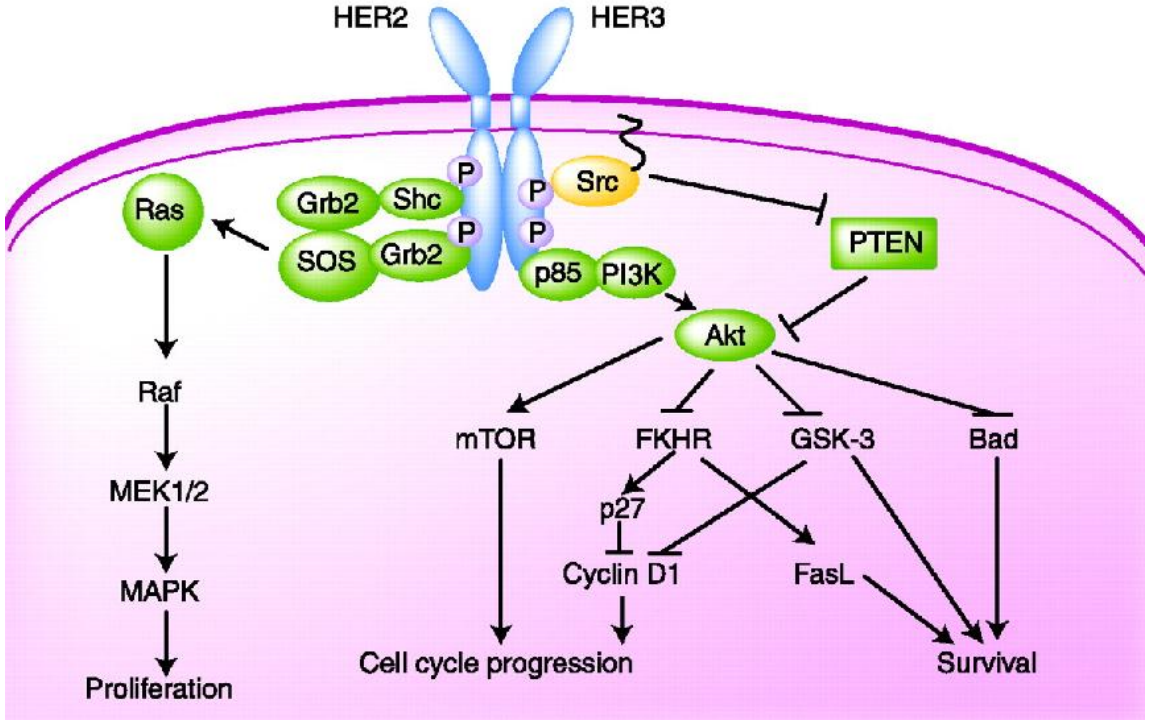
GP2 is Immunogenic & Clinically Effective

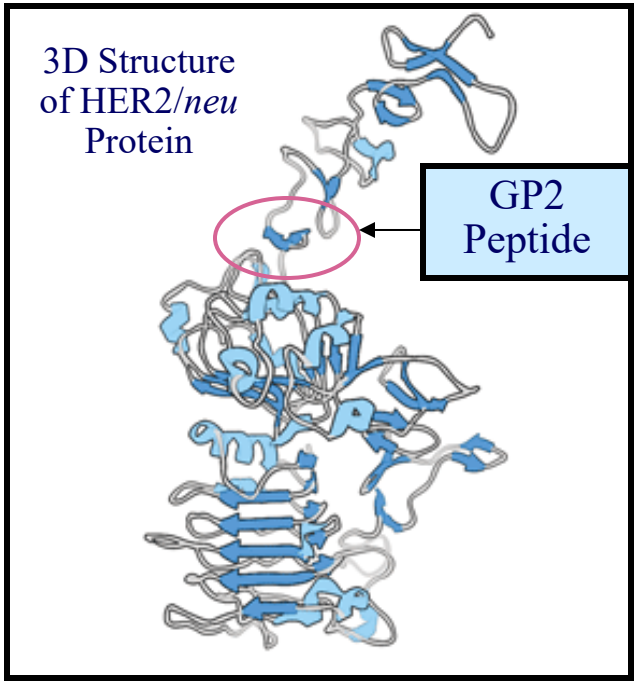
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HER2/*neu* Signaling Pathway Well Studied

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





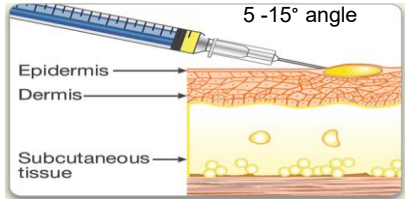
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GP2 Product Description & Mechanism of Action

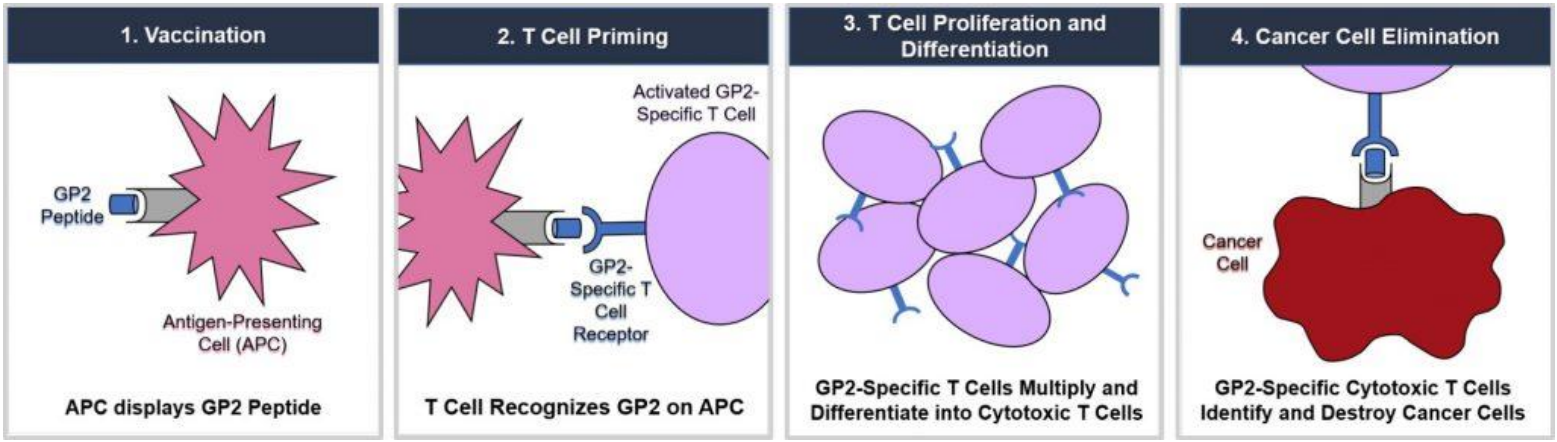
- 9 amino acid transmembrane peptide segment of HER2/*neu* protein
- Intradermal injection in combination with an FDA-approved immunoadjuvant GM-CSF, following 1st year of Herceptin treatment in Adjuvant Setting

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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GP2 Phase III Trial – FLAMINGO-01:

Strategy – Conservatively Reproduce Phase IIb Trial in Larger Population

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Flamingo-01 - Phase III Trial Flamingo-01

- Approximately 180 sites are active
- 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
  - 1st commercial lot completed - large scale manufacturing, packaging, and marketing
- Additional activities/milestones:
  - Phase III clinical trial progress and open label data is being presented at major conferences – AACR, ASCO
  - Licensing discussions accelerating 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

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Flamingo-01 - Phase III Trial Schema

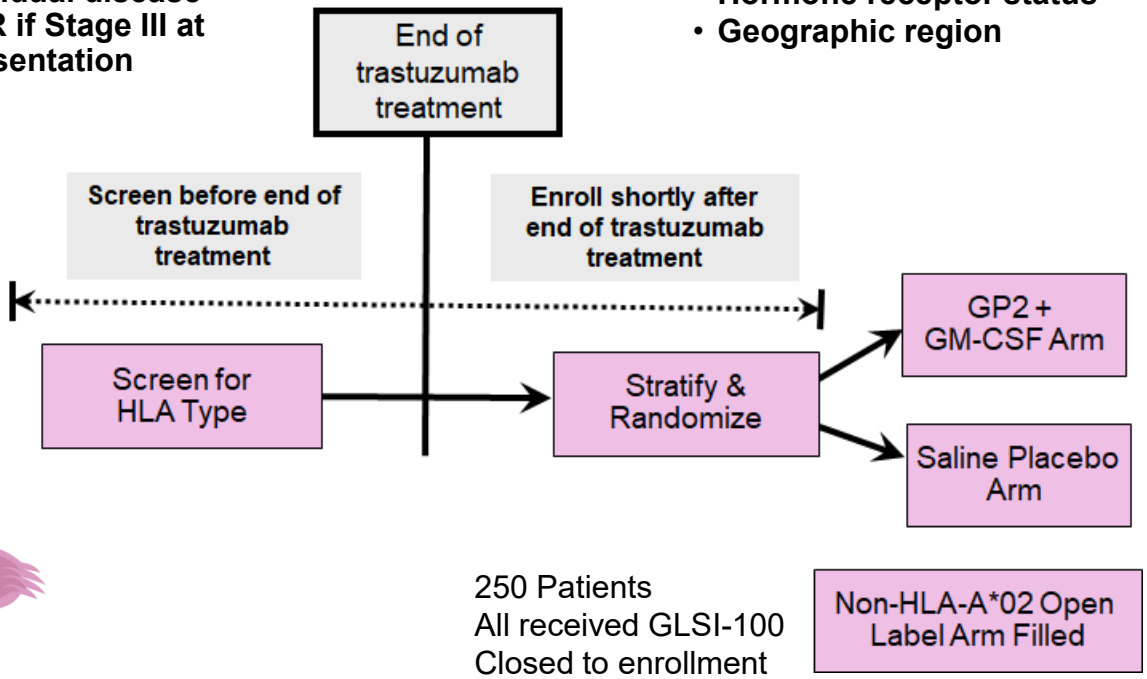
Phase III Trial Schema

Major Screening Criteria:

- **HER2/*neu* 3+ and HLA type**
- **Residual disease**
- **pCR if Stage III at presentation**

Stratified by:

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



Interim Analysis Design

New Interim Design:

- Combining all new patients into one randomized arm independent of HLA type
- More than doubling of enrollment and event rate
- Continuation of enrollment until an event driven interim analysis is conducted and the appropriate size of each arm can be further assessed
- First interim analysis: 28 events, HR = 0.55
- Added second interim analysis
- Regulatory review continues

- Potential for multiple pathways for marketing approval of GLSI-100 and a doubling of market
- Publishing data from open label arm at conferences as data matures

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Derisked Phase III Trial

The Phase III clinical trial has been derisked by:

- Increasing the size of the study, which would increase the power of the study thus decreasing the risk by designing the study to assume more recurrences with a higher HR even though fewer recurrences may be anticipated and observed
- By increasing the original FLAMINGO-01 trial design HR = 0.3 to a design HR = 0.55 and by doubling the events required to trigger the first interim analysis from 14 to 28 events, the probability of success or power at the first interim analysis, if a lower study result HR = 0.3 is realized, increases from less than 20% to more than 85%.
- This increase in power at the first interim, when the study result HR is lower than the design HR, is possible due to the combination of both HLA types, while the more than double event rate at 2.22x offsets the doubling of the events required to trigger this first interim analysis.
  - Non-HLA-A*02 patients represent about 55% of the population. Combining all HLAs increases the enrollment rate by 122% (55%/45% = 122%), resulting in a 2.22x faster enrollment rate, which proportionately increases the event rate
- Continuing to enroll past the interim analyses so that the current momentum at the clinical sites continues by increasing the size of the study to up to 2,000 patients
  - The first interim results could be achieved with less than 2,000 patients enrolled and the results may affect or alter the design of the second interim
  - Endpoints can be analyzed by individual HLA types as well as one combined group of all HLA types and given that each patient has 2 HLA-A alleles, one from each parent, there are multiple analyses that can be conducted and thus multiple pathways to filing a BLA in the US with much higher probabilities of success at each opportunity for analysis
- Using a recently manufactured GP2 commercial drug product lot in FLAMINGO-01

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New Design May Double the Market for GLSI-100

Commercial benefits of combining all non-HLA-A*02 and HLA-A*02 patients into blinded arms:

- The study is now designed and sized to improve the probability of success, to attract the interest of sophisticated investors and pharma companies, and to maximize the chances that the Company could file a BLA after interim analysis 1, after interim analysis 2, or after the end of the study
- The Company plans to now leverage the increased enrollment rate resulting from the combination of all HLA types together with the following:
  - The very high interest from patients and clinicians which has led to approximately 180 clinical trial sites in the US and Europe
  - The currently trending low event rate
  - The efficient cost structure and low burn rate that the Company has successfully funded through small capital raises
    - The Company's annual burn rate was approximately $7 million in 2024 and 2023 and $10 million in 2025
    - This capital raising strategy may provide a bridge to non-dilutive funding, such as strategic/licensing partnerships or debt/royalty financing vehicles, that would further fund FLAMINGO-01 and potential commercial launch activities

Doubling the market for GLSI-100 to potentially $10 billion in revenue per year by accelerating the clinical development of the non-HLA-A*02 population.

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FLAMINGO-01 - Hallmarks of a Large Pharma Phase III Trial

Comparison of FLAMINGO-01 to Katherine (Kadcyla) and Destiny Breast-05 (Enhertu):

- By doubling the number of events to trigger an interim and increasing the HR to 0.55, which is offset by the more than doubling event rate due to the higher enrollment rate, and may or may not alter time lines, the probability of a positive study outcome can be increased substantially.
- The Katherine study which compared Kadcyla to Herceptin breast cancer treatment in the adjuvant setting after surgery in the residual disease population assumed a design HR = 0.75 but realized a lower study result HR at the first interim of 0.5, which led to a sufficiently low p value and strong enough statistical significance to warrant approval for Kadcyla in the adjuvant setting following submission of interim data to the FDA. Approximately 1,486 patients were enrolled, 256 events were observed at the interim analysis, and 385 events were observed at the final analysis.
- The Destiny Breast-05 study which compared Enhertu to Kadcyla breast cancer treatment in the adjuvant setting after surgery, in a higher risk residual disease population than Katherine, assumed a design HR = 0.675 but realized a lower study result HR at the first interim of 0.5, which led to a sufficiently low p value and strong enough statistical significance to warrant approval for Enhertu in the adjuvant setting following submission of interim data to the FDA. Approximately 1,635 patients were enrolled and 153 events were observed at the interim analysis.
- GLSI-100 by contrast has shown a study result HR = 0.2 in the Phase IIb clinical trial for HLA-A*02 patients.
  - In the 250 patient non-HLA-A*02 open label arm of FLAMINGO-01, which is now fully enrolled and where all patients received GLSI-100, a Q1 2026 preliminary analysis of recurrence rates after the PIS is completed shows an approximately 70-80% reduction in recurrence rate or a HR = 0.2-0.3 when calculated by various methods.
  - This data is early and will continue to mature over time. This low event rate is supported by immune response data that was recently published at AACR and ASCO conferences in 2026.

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Non-HLA-A*02 Open Label Poster at AACR 2026 by Steering Committee

American Association for Cancer Research®, April 17-22, 2026 CT138

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

Snehal S. Patel[1], Jaye Thompson[1], F. Joseph Daugherty[1], Francois-Clement Bidard[2], William J. Gradishar[3], Marcus Schmidt[4], Miguel Martin[5], Joyce A. O'Shaughnessy[6], Hope S. Rugo[7], Cesar A. Santa-Maria[8], Laura M. Spring[9], and Mothaffar F. Rimawi[10]

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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

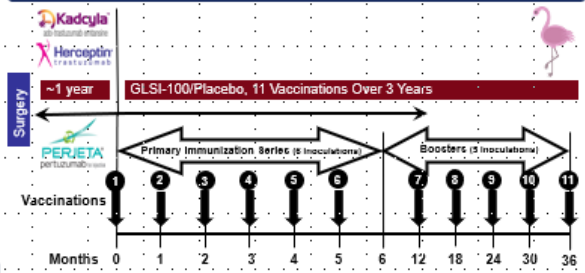
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FLAMINGO TREATMENT



- 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.

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Non-HLA-A*02 Open Label Poster at ASCO 2026 by Steering Committee

American Society of Clinical Oncology®, May 29 – June 2, 2026 LBA538

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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Baylor College of Medicine – Dan L. Duncan Comprehensive Cancer Center

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

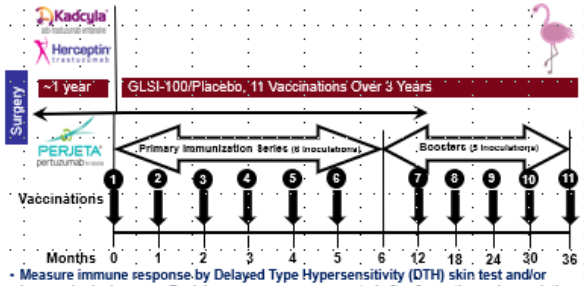
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TABLE 1: INJECTION SITE REACTION TO GLSI-100 BY HLA

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.

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Comparing Non-HLA-A*02 Data to Phase IIb Study

Preliminary Flamingo-01 data available in Q1 2026 is summarized in a blinded manner. This summary may not reflect results at the end of the study.

- 250 patient non-HLA-A*02 arm is now fully enrolled - all patients received GLSI-100, which is 5 times more treated patients and recurrence rate data 50 patients treated in the Phase IIb trial
- Primary Immunization Series (PIS) is first 6 GLSI-100 injections over first 6 months leading to peak protection, followed by 5 booster injections every 6 months providing longer-term protection.
  - Preliminary analysis of recurrence rates after the PIS is completed shows an approximately 70-80% reduction in recurrence rate.
  - This observation is trending similarly to the Phase IIb trial results and hazard ratio where HLA-A*02 patients were treated and where breast cancer recurrences were reduced up to 80% compared to a 20-50% reduction in recurrence rate by other approved products.
  - The immune response at baseline prior to any GLSI-100 treatment, the increasing immune response during the PIS, and the safety profile of non-HLA-A*02 patients is trending similarly to the HLA-A*02 arms of FLAMINGO-01 and to the Phase IIb study.
  - 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, $p < 0.001$).
  - 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 and that GP2 specific T cells may exist in some patients prior to any treatment with GLSI-100, which was also observed in the Phase IIb trial and is being observed in the blinded HLA-A*02 randomized arms of FLAMINGO-01.

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Expand by HLA - GP2-HLA Observed & Predicted Prevalence

Preliminary Flamingo-01 data available to date is summarized in a blinded manner. This summary may not reflect results at the end of the study.

- Across all screened patients, HLA-A*02 prevalence is about 46%. The double HLA-A*02 prevalence, in patients who have received HLA-A*02 alleles from both parents, is about 8%. The HLA-A*03, HLA-A*24, and HLA-A*01 prevalences are about 20-25% for each allele. The HLA-A*11, HLA-A*68, HLA-A*29, and HLA-A*30 prevalences are about 9-12% for each allele.
- In those screened patients who self-report race as:
  - White - HLA-A*02 genes are prevalent in 50% of the patients
  - Hispanic or Latino - HLA-A*02 alleles are prevalent in 50% of the patient
  - Black or African-American - HLA-A*02 alleles are prevalent in 40% of the patients
  - Asian - HLA-A*02 alleles are prevalent in 17% of the patients

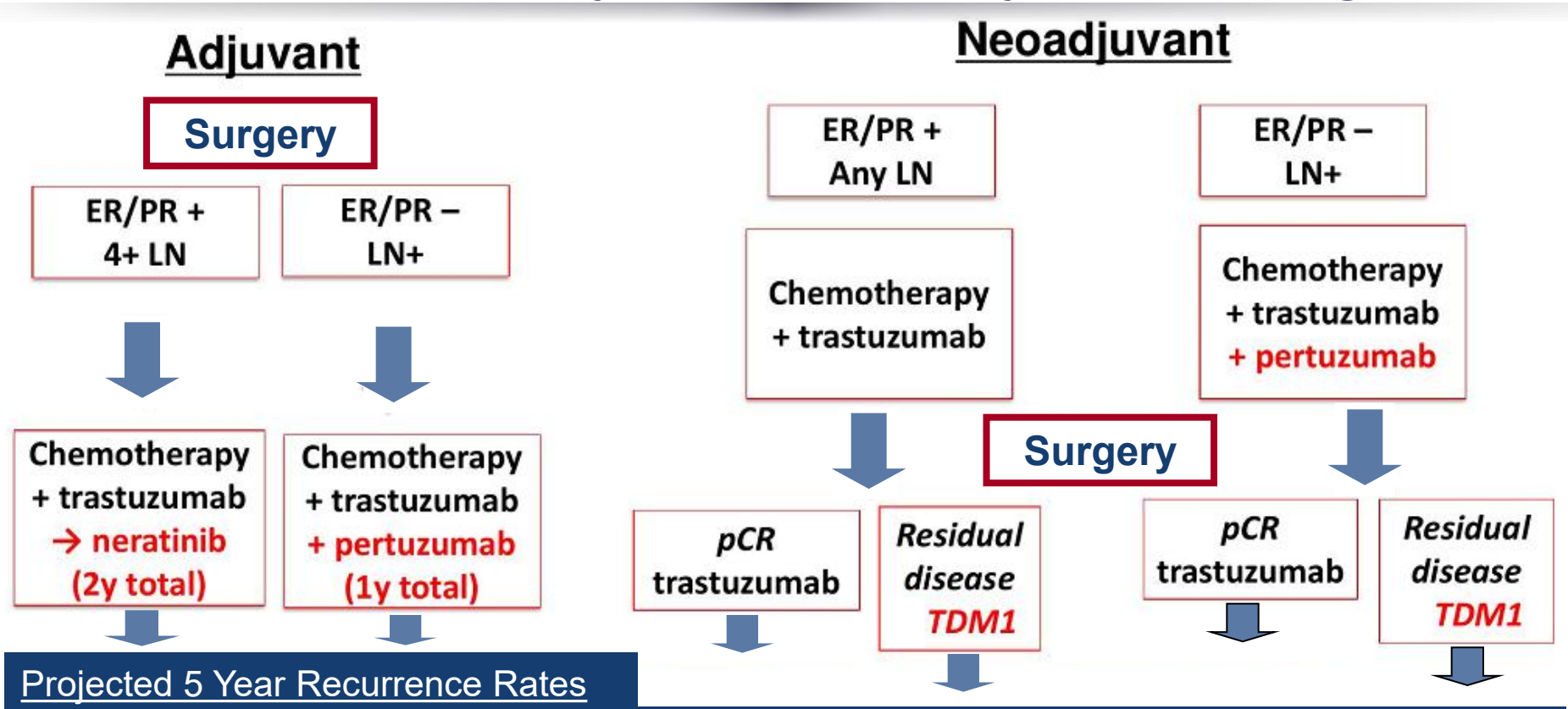
Frequency of Class I MHC alleles HLA in the North America - Data from HLA Matchmaker

Allele	White	Allele	Black	Allele	Hispanic	Allele	Asian/ Pacific
A*02:01	45.6%	C*04:01	29.0%	A*02:01	37.1%	A*11:01	38.4%
C*07:01	27.7%	C*07:01	25.4%	C*04:01	25.4%	A*24:02	33.7%
A*01:01	27.4%	C*06:02	23.0%	A*24:02	24.9%	C*07:02	33.3%
A*03:01	23.8%	A*02:01	22.3%	C*07:02	24.2%	C*01:02	27.7%
C*07:02	21.5%	A*23:01	20.7%	C*07:01	20.8%	A*33:03	23.3%
C*04:01	21.2%	C*02:02	19.0%	C*03:04	14.4%	C*08:01	21.6%
B*44:02	20.2%	A*03:01	18.7%	A*03:01	14.3%	C*03:04	19.9%
B*07:02	18.1%	C*07:02	18.1%	B*07:02	13.2%	A*02:01	18.1%

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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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GP2 Specific & Secondary Immune Response TCR Sequencing

Multiple Open Label Immune Response Assessments are Planned to Potentially Identify GP2 Specific T cells, Biomarkers, Booster Strategies, and Early Recurrers

1. Delayed Type Hypersensitive (DTH) skin test for in vivo immune response to GP2 (20% of dose)
2. Injection site reaction measurements which are correlated to DTH in Phase IIb trial
3. Single cell sequencing of T cells resulting from spiked dendritic cells
4. TCR sequencing from frozen blood samples over course of Phase III trial (Example: extensive sequencing of COVID-19 infection & vaccinated patient samples)
5. Potential for ctDNA analysis of plasma
6. Potential for Elispot assay for quantification of functional GP2 specific T cells

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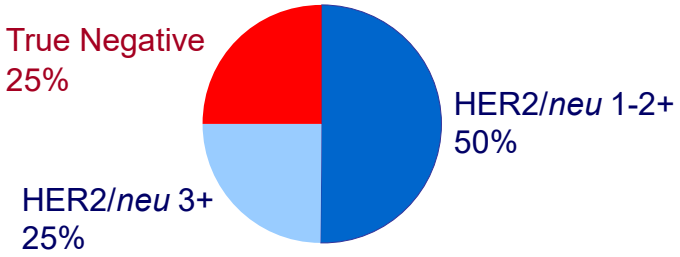
GP2 Commercial Opportunity

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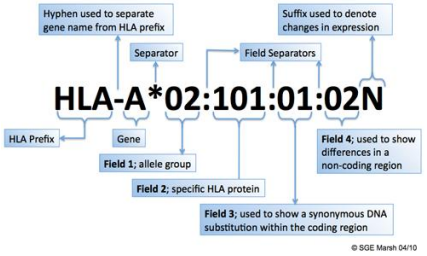
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Potential Indications of GP2 & Herceptin in Various Populations in Neoadjuvant Setting

- 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



- 12.5% of 700k new US and EU breast cancer patients per year could lead to up to 88k new patients per year for GP2 (12.5% * 700k new pts = 88k pts/yr for all HLA types)
- 12.5% of 9.5m long term US and EU breast cancer survivors could be candidates for GP2 (Sources: American Cancer Society, Economic Impact, & European Cancer Information System 2025)

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Commercial Opportunity for GP2 in Breast Cancer in US/EU

- **1 in 8 U.S. women (12.8%) will develop invasive breast cancer over her lifetime, with 317k new breast cancer patients per year in 2025 (400k in EU)**
- **An estimated 42k female breast cancer deaths will occur in the US in 2025**
- **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 (4m as of 2025, 5.5m in EU)**
- **Herceptin/Perjeta/Nerlynx/Kadcyla pricing from $75k - $125k per patient per year**
- **11 doses over 3 years in initial indication**

	Herceptin	GP2
US & EU Market Potential (Size = 9.5m current breast cancer survivors and 700k new patients per year)		
HER2/*neu* Expressors (1-3+)	25% (3+)	25-75% (1-3+)
HLA Type	100%	50-80% (2/3/24/26)
Residual Disease or High Risk pCR	50%	50%
Target Market Potential	12.5%	6.25 - 30%
Theoretical New Patients per Year	35,250	44,000 – 210,000 in US/EU
Adjuvant Patients Treated per Year (est. from sales)	27,000 – 40,000	88k - 420k pts/yr for all HLA types.
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	US Revenue could double when adding EU market and quadruple when adding all HLA types.
Metastatic Breast Cancer	$4-5	

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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.

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

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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

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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
  - Commercial 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
- 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

Recently granted Fast Track designation by FDA

Greenwich LifeSciences

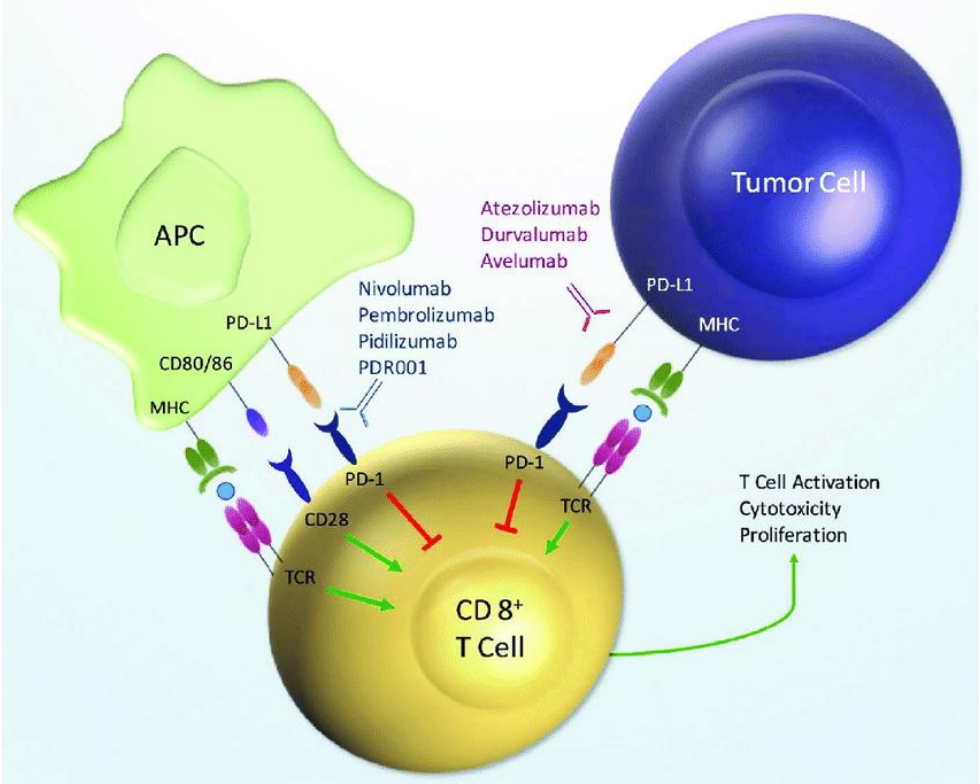
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GLSI Strategy is to Conduct Additional GP2 Trials

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!

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



Flamingo-01 - Current Phase III Trial with Interim Analysis: 9 amino acid HER2/*neu* peptide + GM-CSF immunotherapy for breast cancer in HER2/*neu* positive patients following neoadjuvant, surgery, & adjuvant Herceptin or Kadcyla, led by Baylor & consortium of prominent networks - up to 180 sites in US & EU

- Conservative design of Phase III trial to reproduce Phase IIb results
- Phase IIb Trial Results: Randomized, multi-center (16 centers), placebo-controlled, substantial reduction in recurrence rate, 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* low patients with Herceptin - increase market from 25% to 75%
  - ✓ Other HLA types – increase from 40-50% up to 80-100% of all patients
  - Combination with CD4/CD8 peptides and checkpoints
  - Other HER2/*neu* cancers
- NASDAQ Ticker "GLSI": Raised $60m since IPO

Recently granted Fast Track designation by FDA

Greenwich LifeSciences

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GLSI Sponsorship of 5k Race in Houston each October

susan g. komen race FOR THE cure®

Research

that provides new hope through lifesaving discoveries. Funding breakthroughs that give more time to everyone in their fight against breast cancer.

Care

that ensures all have access to quality screening, diagnosis and treatment for breast cancer. Offering patient support, treatment assistance, even childcare and transportation services.

Community

to support everyone, no matter where they are in their breast cancer journey. Providing a safe place to share, grieve, support and find strength forward.

Action

through advocacy, fighting for government funding and critical patient support and research. We fight for the rights of patients among policymakers and compassionate care for everyone.



Greenwich LifeSciences

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