UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **November 9, 2021**

Greenwich LifeSciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39555**	**20-5473709**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I. R. S. Employer Identification No.)

3992 Bluebonnet Dr, Building 14
Stafford, TX 77477
(Address of principal executive offices, including ZIP code)

(832) 819-3232
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.001 par value	GLSI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Greenwich LifeSciences, Inc. (the "Company") intends to conduct meetings with third parties in which its corporate slide presentation ("Company Presentation") will be presented. The Company Presentation is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 7.01 by reference. In addition, the Company released a press release attached to this Current Report on Form 8-K as Exhibit 99.2 and incorporated into this Item 7.01 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information furnished under this Item 7.01 of this Current Report on Form 8-K and the exhibit attached hereto are deemed to be "furnished" and shall not be deemed "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information and exhibit be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Corporate Presentation of Greenwich LifeSciences, Inc.
99.2	Press Release dated November 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Greenwich LifeSciences, Inc.

Date: November 10, 2021

By: */s/ Snehal Patel*
Snehal Patel
Chief Executive Officer

GREENWICH LIFESCIENCES

View webcast here

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

Safe Harbor Statement

This document is the property of Greenwich LifeSciences, Inc., (the "Company" or "Greenwich LifeSciences"). This document is non-directive in nature (contains no recommendations regarding financial actions related to the Company). This document is not to be copied or delivered to any other person or used for any other purpose without the prior consent of the Company.

This presentation contains "forward-looking statements" within the meaning of the "safe-harbor" provisions of the Private Securities Litigation Reform Act of 1995.

These statements are identified by the use of words "could", "believe", "anticipate", "intend", "estimate", "expect", "may", "continue", "predict", "potential" and similar expressions that are intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that could cause the actual results of the Company to differ materially from the results expressed or implied by such statements including, but not limited to: risks associated with the success of clinical trials, research and development programs, regulatory approval processes for clinical trials, competitive technologies and products, intellectual property rights and the need for additional financing.

Accordingly, although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. Except as required by law, the Company disclaims any obligations to publicly update or release any revisions to the forward-looking information contained in this presentation, whether as a result of new information, future events or otherwise, after the date of this presentation or to reflect the occurrence of unanticipated events.

The information contained herein is based on sources, which we believe to be reliable, but is not guaranteed by us as being accurate and does not purport to be a complete statement or summary of the available data. Although every effort has been made to assure the accuracy of the statements in this presentation, we make no representation or warranty as to the accuracy or completeness of the statements in this presentation. Furthermore, we make forward-looking statements in this report about the Company's plans, objectives, expectations, and intentions.

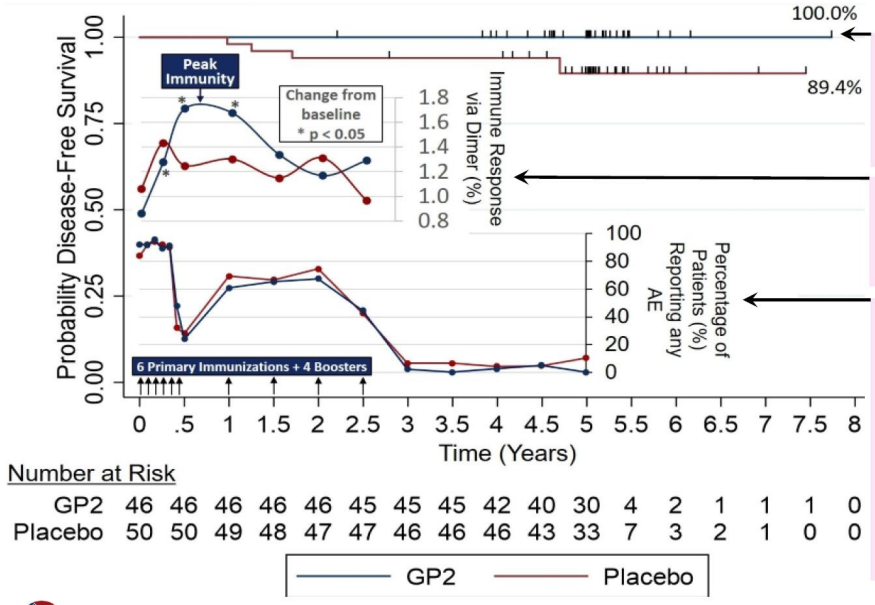
This presentation is not an offer to sell any securities of the Company and is not to be used in connection with any offer to sell or any inquiry about or evaluation of any securities of the Company. Any such sale, or opportunity, will be subject to appropriate documentation and due diligence.

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

- Planned Phase III Trial: 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
- Phase IIb Trial Results: 0% recurrences, if fully immunized, versus 11% placebo recurrence rate in 96 patients, peak immunity after 6 months, minimal to no side effects, no SAEs attributable to GP2 (*p = 0.0338*)
  - Randomized, multi-center (16 centers), placebo-controlled, closed in 2018 with median 5 years follow-up led by MD Anderson
- Regulatory: FDA reviewed Phase III trial protocol and CMC – finalizing Phase III trial protocol, interim analysis added
- Manufacturing: Straight forward, Phase III lot near completion
- 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, as of 9/1/21, best performing biotech IPO of 307 IPOs since February 2019 – 661% return (BioPharmCatalyst)

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

Breast Cancer – *Still* a Substantial Unmet Need

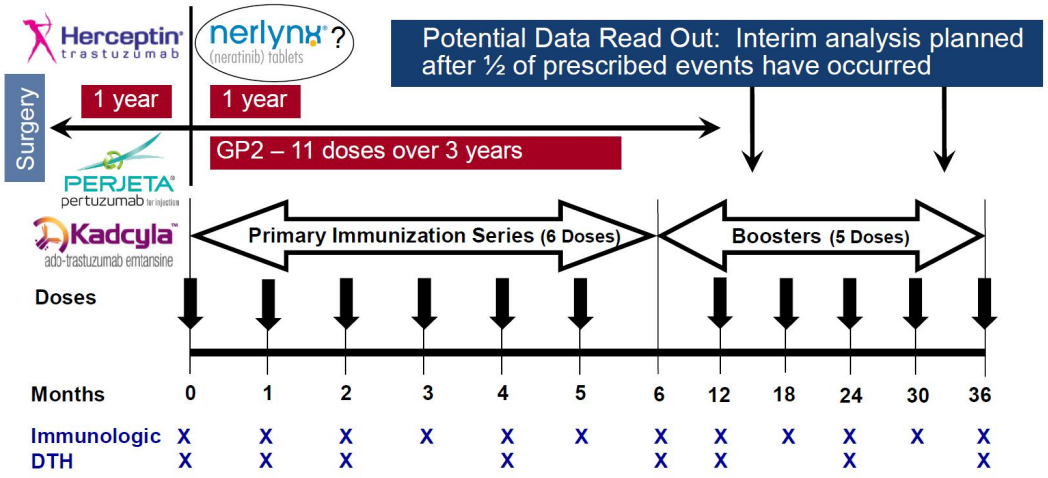
- ***Unmet Need is to address the 50% of recurring patients who do not respond to Herceptin or Kadcyla – an opportunity for GP2.***
- ***Adjuvant Setting: Following breast cancer surgery, HER2/neu 3+ patients receive Herceptin in the first year and then hope that their breast cancer will not recur, with 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.

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

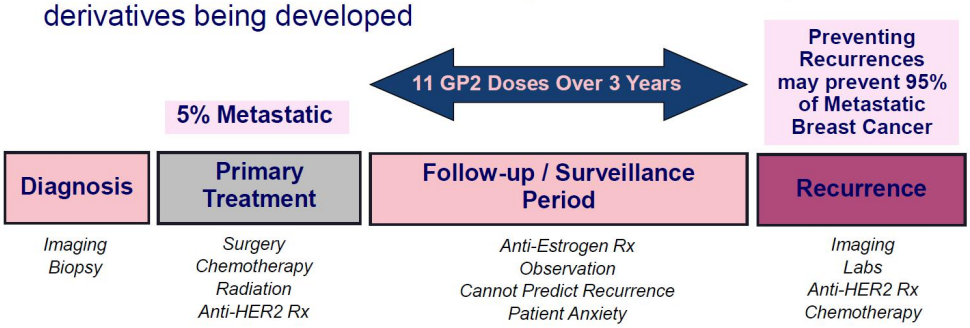
GP2 Phase III Clinical Trial Dosing



- 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

GP2 Market Positioning & Feedback from KOLs

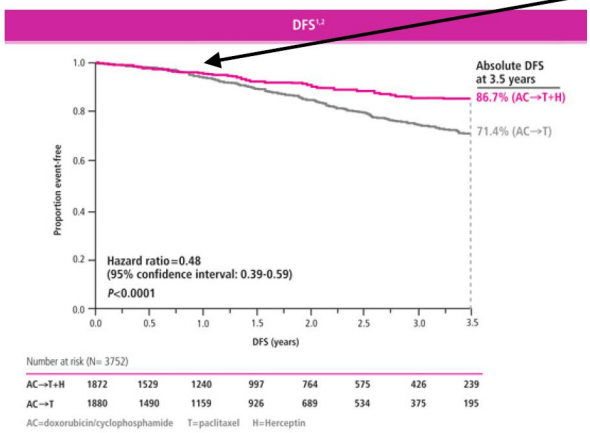
- As only injection site reactions were observed (which speaks to the immunogenicity of GP2) and with no SAEs attributable to GP2, GP2 can be positioned as the final treatment for patients post surgery
- Patients are seeking a de-escalation and a return to normal life free of toxic treatments, especially 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



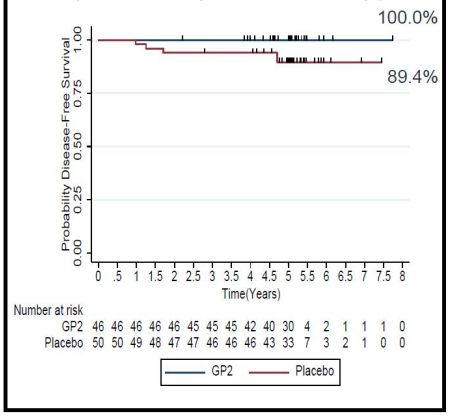
Synergy with Herceptin Alone ** 0% Metastatic Cancer Recurrences

** 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



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



Joint Analysis Trial
*DFS – Disease Free Survival

GP2 Clinical Data:

GP2 is Immunogenic & Clinically Effective

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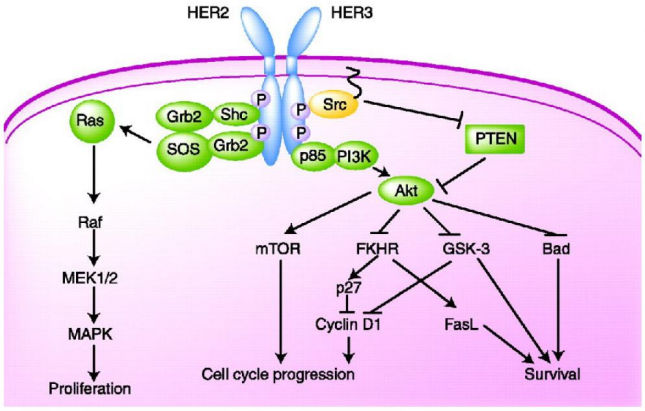
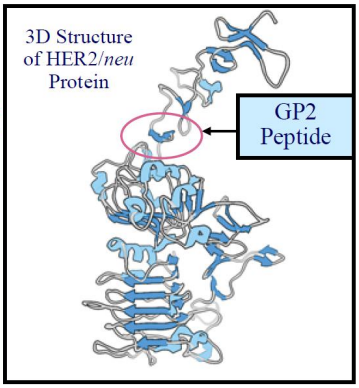
HER2/*neu* Signaling Pathway Well Studied

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





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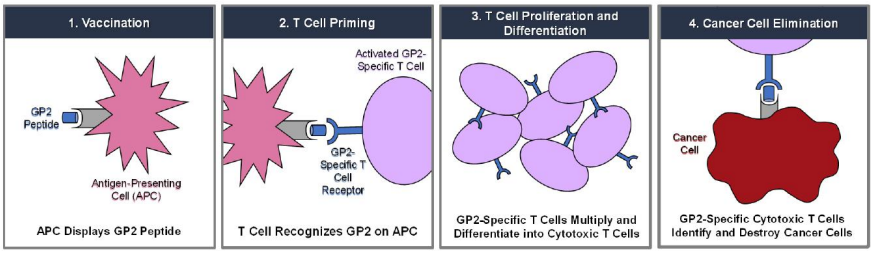
GP2 Product Description & Mechanism of Action

- 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

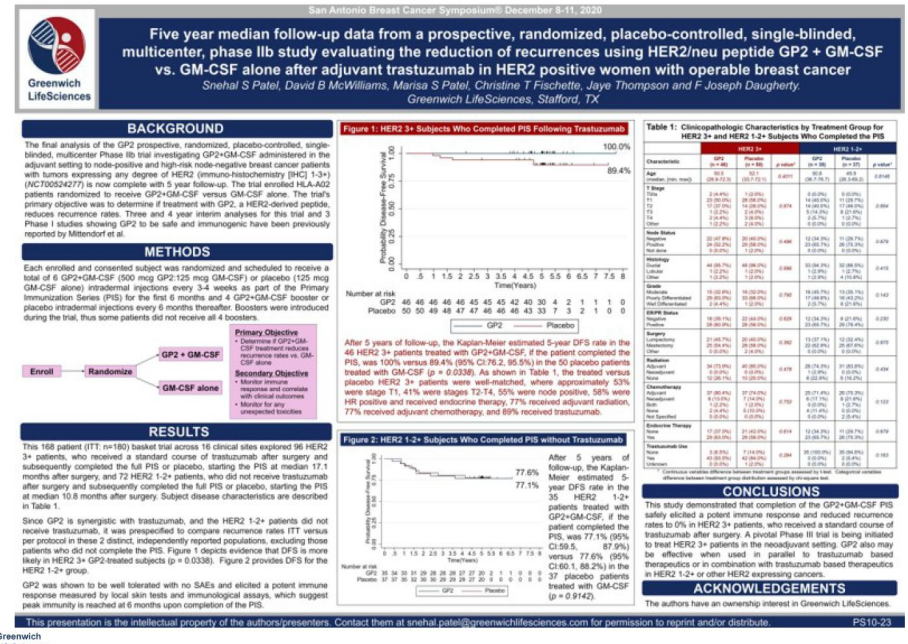
- Given once per month for six months followed by 5 booster doses every 6 months = 11 doses over 3 years
- Mechanism of Action: 4 primary steps, followed by a secondary epitope spreading & broader immune response



Summary of GP2 Completed Trials – N=138 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.	181 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

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



San Antonio Breast Cancer Symposium® December 8-11, 2020

Five year median follow-up data from a prospective, randomized, placebo-controlled, single-blinded, multicenter, phase IIb study evaluating the reduction of recurrences using HER2/neu peptide GP2 + GM-CSF vs. GM-CSF alone after adjuvant trastuzumab in HER2 positive women with operable breast cancer

Snehal S Patel, David B McWilliams, Marisa S Patel, Christine T Fischette, Jaye Thompson and F Joseph Daugherty.
Greenwich LifeSciences, Stafford, TX

BACKGROUND

The final analysis of the GP2 prospective, randomized, placebo-controlled, single-blinded, multicenter Phase IIb trial investigating GP2+GM-CSF administered in the adjuvant setting to node-positive and high-risk node-negative breast cancer patients with tumors expressing any degree of HER2 (immuno-histochemistry [IHC] 1-3+) (*NCT00524277*) is now complete with 5 year follow-up. The trial enrolled HLA-A02 patients randomized to receive GP2+GM-CSF versus GM-CSF alone. The trial's primary objective was to determine if treatment with GP2, a HER2-derived peptide, reduces recurrence rates. Three and 4 year interim analyses for this trial and 3 Phase I studies showing GP2 to be safe and immunogenic have been previously reported by Mittendorf et al.

METHODS

Each enrolled and consented subject was randomized and scheduled to receive a total of 6 GP2+GM-CSF (500 mcg GP2:125 mcg GM-CSF) or placebo (125 mcg GM-CSF alone) intradermal injections every 3-4 weeks as part of the Primary Immunization Series (PIS) for the first 6 months and 4 GP2+GM-CSF booster or placebo intradermal injections every 6 months thereafter. Boosters were introduced during the trial, thus some patients did not receive all 4 boosters.

RESULTS

This 168 patient (ITT: n=180) basket trial across 16 clinical sites explored 96 HER2 3+ patients, who received a standard course of trastuzumab after surgery and subsequently completed the full PIS or placebo, starting the PIS at median 17.1 months after surgery, and 72 HER2 1-2+ patients, who did not receive trastuzumab after surgery and subsequently completed the full PIS or placebo, starting the PIS at median 10.8 months after surgery. Subject disease characteristics are described in Table 1.

Since GP2 is synergistic with trastuzumab, and the HER2 1-2+ patients did not receive trastuzumab, it was prespecified to compare recurrence rates ITT versus per protocol in these 2 distinct, independently reported populations, excluding those patients who did not complete the PIS. Figure 1 depicts evidence that DFS is more likely in HER2 3+ GP2-treated subjects ($p = 0.0338$). Figure 2 provides DFS for the HER2 1-2+ group.

GP2 was shown to be well tolerated with no SAEs and elicited a potent immune response measured by local skin tests and immunological assays, which suggest peak immunity is reached at 6 months upon completion of the PIS.

Figure 1: HER2 3+ Subjects Who Completed PIS Following Trastuzumab

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 ($p = 0.0338$). As shown in Table 1, 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 HR positive and received endocrine therapy, 77% received adjuvant radiation, 77% received adjuvant chemotherapy, and 89% received trastuzumab.

Figure 2: HER2 1-2+ Subjects Who Completed PIS without Trastuzumab

After 5 years of follow-up, the Kaplan-Meier estimated 5-year DFS rate in the 35 HER2 1-2+ patients treated with GP2+GM-CSF, if the patient completed the PIS, was 77.1% (95% CI:59.5, 87.9%) versus 77.6% (95% CI:60.1, 88.2%) in the 37 placebo patients treated with GM-CSF ($p = 0.9142$).

Table 1: Clinicopathologic Characteristics by Treatment Group for HER2 3+ and HER2 1-2+ Subjects Who Completed the PIS

CONCLUSIONS

This study demonstrated that completion of the GP2+GM-CSF PIS safely elicited a potent immune response and reduced recurrence rates to 0% in HER2 3+ patients, who received a standard course of trastuzumab after surgery. A pivotal Phase III trial is being initiated to treat HER2 3+ patients in the neoadjuvant setting. GP2 also may be effective when used in parallel to trastuzumab based therapeutics or in combination with trastuzumab based therapeutics in HER2 1-2+ or other HER2 expressing cancers.

ACKNOWLEDGEMENTS

The authors have an ownership interest in Greenwich LifeSciences.

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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%)	*0.753*	25 (71.4%)	26 (70.3%)	*0.123*
Neoadjuvant	6 (13.0%)	7 (14.0%)		6 (17.1%)	8 (21.6%)	
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%)	*0.294*	35 (100.0%)	35 (94.6%)	*0.163*
Yes	43 (93.5%)	42 (84.0%)		0 (0.0%)	2 (5.4%)	
Unknown	0 (0.0%)	1 (2.0%)		0 (0.0%)	0 (0.0%)	

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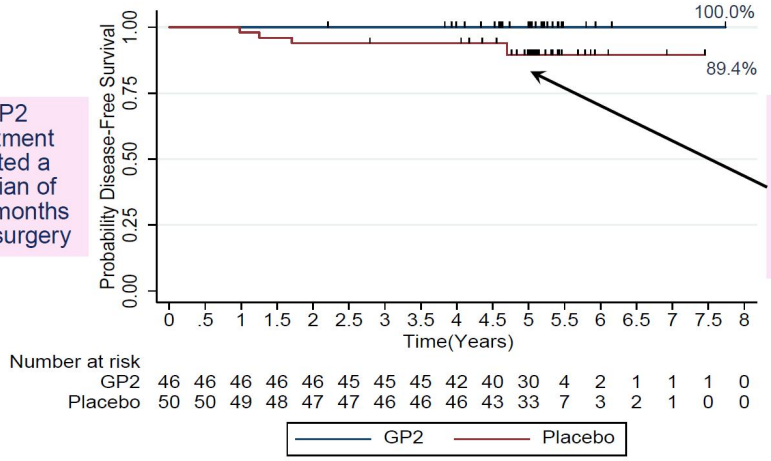
SABCS 2020 – 100% Disease Free Survival

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

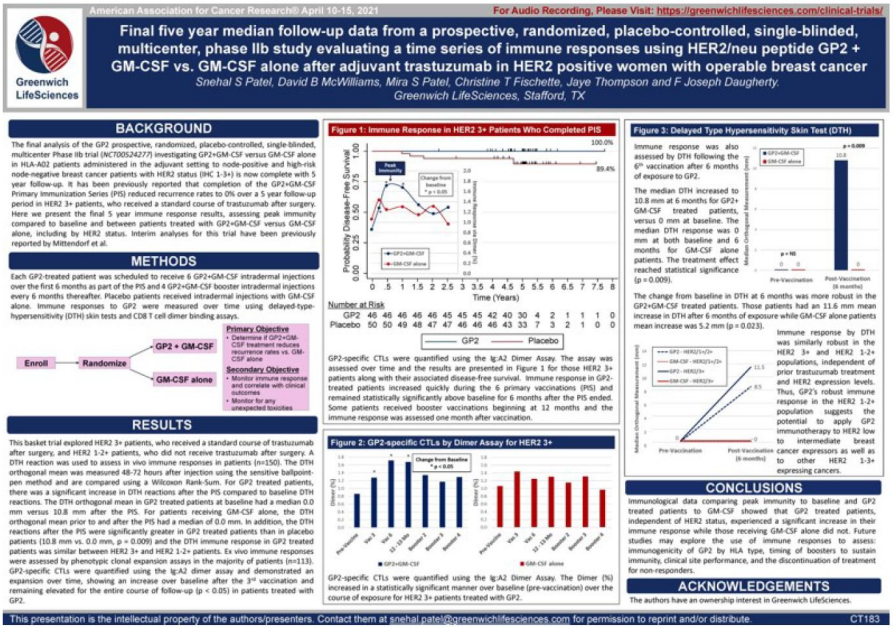
GP2 treatment started a median of 17.1 months after surgery



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*).

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



American Association for Cancer Research® April 10-15, 2021 — For Audio Recording, Please Visit: https://greenwichlifesciences.com/clinical-trials/

Final five year median follow-up data from a prospective, randomized, placebo-controlled, single-blinded, multicenter, phase IIb study evaluating a time series of immune responses using HER2/neu peptide GP2 + GM-CSF vs. GM-CSF alone after adjuvant trastuzumab in HER2 positive women with operable breast cancer

Snehal S Patel, David B McWilliams, Mira S Patel, Christine T Fischette, Jaye Thompson and F Joseph Daugherty.
Greenwich LifeSciences, Stafford, TX

BACKGROUND

The final analysis of the GP2 prospective, randomized, placebo-controlled, single-blinded, multicenter Phase IIb trial (*NCT00524277*) investigating GP2+GM-CSF versus GM-CSF alone in HLA-A02 patients administered in the adjuvant setting to node-positive and high-risk node-negative breast cancer patients with HER2 status (IHC 1-3+) is now complete with 5 year follow-up. It has been previously reported that completion of the GP2+GM-CSF Primary Immunization Series (PIS) reduced recurrence rates to 0% over a 5 year follow-up period in HER2 3+ patients, who received a standard course of trastuzumab after surgery. Here we present the final 5 year immune response results, assessing peak immunity compared to baseline and between patients treated with GP2+GM-CSF versus GM-CSF alone, including by HER2 status. Interim analyses for this trial have been previously reported by Mittendorf et al.

METHODS

Each GP2-treated patient was scheduled to receive 6 GP2+GM-CSF intradermal injections over the first 6 months as part of the PIS and 4 GP2+GM-CSF booster intradermal injections every 6 months thereafter. Placebo patients received intradermal injections with GM-CSF alone. Immune responses to GP2 were measured over time using delayed-type-hypersensitivity (DTH) skin tests and CD8 T cell dimer binding assays.

Enroll → Randomize → GP2 + GM-CSF / GM-CSF alone

Primary Objective
- Determine if GP2+GM-CSF treatment reduces recurrence rates vs. GM-CSF alone

Secondary Objective
- Monitor immune response and correlate with clinical outcomes
- Monitor for any unexpected toxicities

RESULTS

This basket trial explored HER2 3+ patients, who received a standard course of trastuzumab after surgery, and HER2 1-2+ patients, who did not receive trastuzumab after surgery. A DTH reaction was used to assess in vivo immune responses in patients (n=150). The DTH orthogonal mean was measured 48-72 hours after injection using the sensitive ballpoint-pen method and are 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. The DTH orthogonal mean in GP2 treated patients at baseline had a median 0.0 mm versus 10.8 mm after the PIS. For patients receiving GM-CSF alone, the DTH orthogonal mean prior to and after the PIS had a median of 0.0 mm. In addition, the DTH reactions after the PIS were significantly greater in GP2 treated patients than in placebo patients (10.8 mm vs. 0.0 mm, $p = 0.009$) and the DTH immune response in GP2 treated patients was similar between HER2 3+ and HER2 1-2+ patients. Ex vivo immune responses were assessed by phenotypic clonal expansion assays in the majority of patients (n=113). GP2-specific CTLs were quantified using the Ig:A2 dimer assay and demonstrated an expansion over time, showing an increase over baseline after the 3rd vaccination and remaining elevated for the entire course of follow-up ($p < 0.05$) in patients treated with GP2.

Figure 1: Immune Response in HER2 3+ Patients Who Completed PIS

GP2-specific CTLs were quantified using the Ig:A2 Dimer Assay. The assay was assessed over time and the results are presented in Figure 1 for those HER2 3+ patients along with their associated disease-free survival. 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.

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

GP2-specific CTLs were quantified using the Ig:A2 Dimer Assay. The Dimer (%) increased in a statistically significant manner over baseline (pre-vaccination) over the course of exposure for HER2 3+ patients treated with GP2.

Figure 3: Delayed Type Hypersensitivity Skin Test (DTH)

Immune response was also assessed by DTH following the 6th vaccination after 6 months of exposure to GP2.

The median DTH increased to 10.8 mm at 6 months for GP2+GM-CSF treated patients, versus 0 mm at baseline. The median DTH response was 0 mm at both baseline and 6 months for GM-CSF alone patients. The treatment effect reached statistical significance ($p = 0.009$).

The change from baseline in DTH at 6 months was more robust in the GP2+GM-CSF treated patients. Those patients had an 11.6 mm mean increase in DTH after 6 months of exposure while GM-CSF alone patients mean increase was 5.2 mm ($p = 0.023$).

Immune response by DTH was similarly robust in the HER2 3+ and HER2 1-2+ populations, 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 breast cancer expressors as well as to other HER2 1-3+ expressing cancers.

CONCLUSIONS

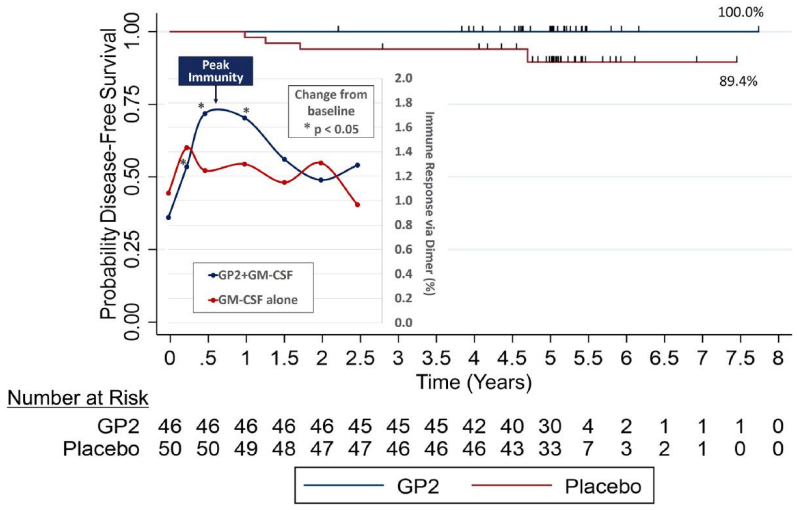
Immunological data comparing peak immunity to baseline and GP2 treated patients to GM-CSF showed that GP2 treated patients, independent of HER2 status, experienced a significant increase in their immune response while those receiving GM-CSF alone did not. Future studies may explore the use of immune responses to assess: immunogenicity of GP2 by HLA type, timing of boosters to sustain immunity, clinical site performance, and the discontinuation of treatment for non-responders.

ACKNOWLEDGEMENTS

The authors have an ownership interest in Greenwich LifeSciences.

AACR 2021 – Immune Response Peaks at 6 Months

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



GP2-specified CTLs were quantified using the Ig:A2 Dimer Assay. The assay was assessed over time and the results are presented in Figure 1 for those HER2 3+ patients along with their associated disease-free survival. 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 Response Assays

Dimer Binding Assay

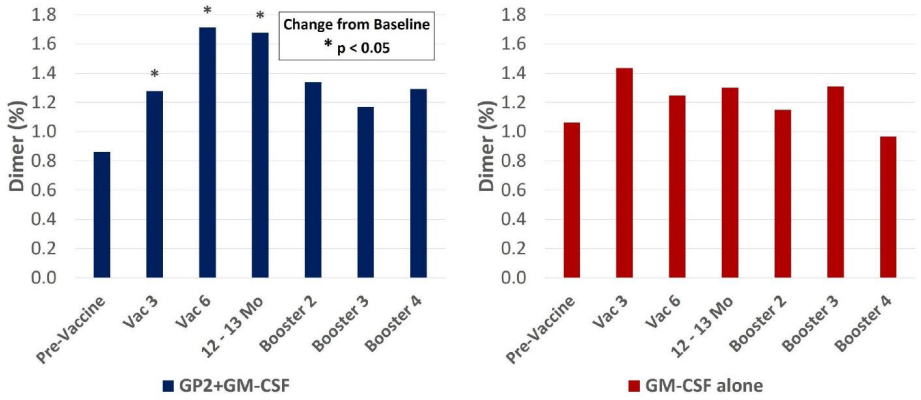
The Dimer Binding Assay detects the percentage of GP2 specific killer T cells that can kill recurring cancer cells. Ex vivo immune response was assessed over 2.5 years with blood draws at baseline, then after the 3rd and 6th immunizations in the Primary Immunization Series, and then after each booster. 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

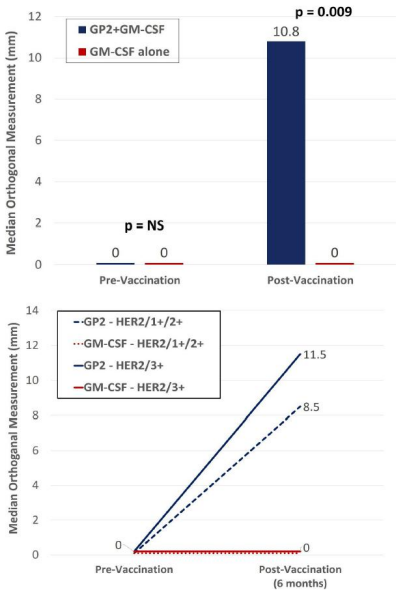
Figure 2: GP2-specific CTLs by Dimer Assay for HER2 3+



The same Dimer Binding Assay data for HER2 3+ patients is shown as in Figure 1, where the GP2 treated patients showed statistically significant dimer readings versus baseline (pre-vaccination) at 3, 6, and 12-13 months.

AACR 2021 – Immune DTH Skin Test

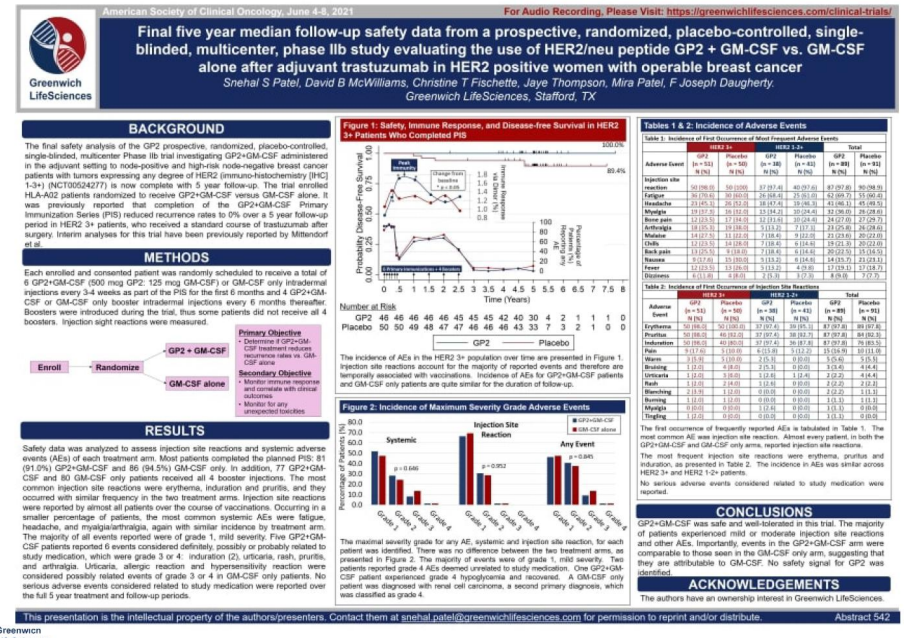
Figure 3: Delayed Type Hypersensitivity Skin Test (DTH)



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.

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



American Society of Clinical Oncology, June 4-8, 2021 — For Audio Recording, Please Visit: https://greenwichlifesciences.com/clinical-trials/

Final five year median follow-up safety data from a prospective, randomized, placebo-controlled, single-blinded, multicenter, phase IIb study evaluating the use of HER2/neu peptide GP2 + GM-CSF vs. GM-CSF alone after adjuvant trastuzumab in HER2 positive women with operable breast cancer

Snehal S Patel, David B McWilliams, Christine T Fischette, Jaye Thompson, Mira Patel, F Joseph Daugherty.
Greenwich LifeSciences, Stafford, TX

BACKGROUND

The final safety analysis of the GP2 prospective, randomized, placebo-controlled, single-blinded, multicenter Phase IIb trial investigating GP2+GM-CSF administered in the adjuvant setting to node-positive and high-risk node-negative breast cancer patients with tumors expressing any degree of HER2 (immuno-histochemistry [IHC] 1-3+) (NCT00524277) is now complete with 5 year follow-up. The trial enrolled HLA-A02 patients randomized to receive GP2+GM-CSF versus GM-CSF alone. It was previously reported that completion of the GP2+GM-CSF Primary Immunization Series (PIS) reduced recurrence rates to 0% over a 5 year follow-up period in HER2 3+ patients, who received a standard course of trastuzumab after surgery. Interim analyses for this trial have been previously reported by Mittendorf et al.

METHODS

Each enrolled and consented patient was randomly scheduled to receive a total of 6 GP2+GM-CSF (500 mcg GP2: 125 mcg GM-CSF) or GM-CSF only intradermal injections every 3-4 weeks as part of the PIS for the first 6 months and 4 GP2+GM-CSF or GM-CSF only booster intradermal injections every 6 months thereafter. Boosters were introduced during the trial, thus some patients did not receive all 4 boosters. Injection sight reactions were measured.

Enroll → Randomize → GP2 + GM-CSF / GM-CSF alone

Primary Objective
- Determine if GP2+GM-CSF treatment reduces recurrence rates vs. GM-CSF alone

Secondary Objective
- Monitor immune response and correlate with clinical outcomes
- Monitor for any unexpected toxicities

RESULTS

Safety data was analyzed to assess injection site reactions and systemic adverse events (AEs) of each treatment arm. Most patients completed the planned PIS: 81 (91.0%) GP2+GM-CSF and 86 (94.5%) GM-CSF only. In addition, 77 GP2+GM-CSF and 80 GM-CSF only patients received all 4 booster injections. The most common injection site reactions were erythema, induration and pruritis, and they occurred with similar frequency in the two treatment arms. Injection site reactions were reported by almost all patients over the course of vaccinations. Occurring in a smaller percentage of patients, the most common systemic AEs were fatigue, headache, and myalgia/arthralgia, again with similar incidence by treatment arm. The majority of all events reported were of grade 1, mild severity. Five GP2+GM-CSF patients reported 6 events considered definitely, possibly or probably related to study medication, which were grade 3 or 4: induration (2), urticaria, rash, pruritis, and arthralgia. Urticaria, allergic reaction and hypersensitivity reaction were considered possibly related events of grade 3 or 4 in GM-CSF only patients. No serious adverse events considered related to study medication were reported over the full 5 year treatment and follow-up periods.

Figure 1: Safety, Immune Response, and Disease-free Survival in HER2 3+ Patients Who Completed PIS

The incidence of AEs in the HER2 3+ population over time are presented in Figure 1. Injection site reactions account for the majority of reported events and therefore are temporally associated with vaccinations. Incidence of AEs for GP2+GM-CSF patients and GM-CSF only patients are quite similar for the duration of follow-up.

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.

Tables 1 & 2: Incidence of Adverse Events

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

Adverse Event	HER2 3+ GP2 (n = 51) N (%)	HER2 3+ Placebo (n = 50) N (%)	HER2 1-2+ GP2 (n = 38) N (%)	HER2 1-2+ Placebo (n = 43) N (%)	Total GP2 (n = 89) N (%)	Total 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)	18 (47.4)	19 (46.3)	41 (46.1)	45 (49.5)
Myalgia	19 (37.3)	16 (32.0)	15 (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)	8 (8.0)	2 (5.3)	3 (7.3)	8 (9.0)	7 (7.7)

Table 2: Incidence of First Occurrence of Injection Site Reactions

Adverse Event	HER2 3+ GP2 (n = 51) N (%)	HER2 3+ Placebo (n = 50) N (%)	HER2 1-2+ GP2 (n = 38) N (%)	HER2 1-2+ Placebo (n = 43) N (%)	Total GP2 (n = 89) N (%)	Total 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)	4 (10.5)	5 (12.2)	13 (14.6)	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.

No serious adverse events considered related to study medication were reported.

CONCLUSIONS

GP2+GM-CSF was safe and well-tolerated in this trial. The majority of patients experienced mild or moderate injection site reactions and other AEs. Importantly, events in the GP2+GM-CSF arm were comparable to those seen in the GM-CSF only arm, suggesting that they are attributable to GM-CSF. No safety signal for GP2 was identified.

ACKNOWLEDGEMENTS

The authors have an ownership interest in Greenwich LifeSciences.

 Abstract 542

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

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

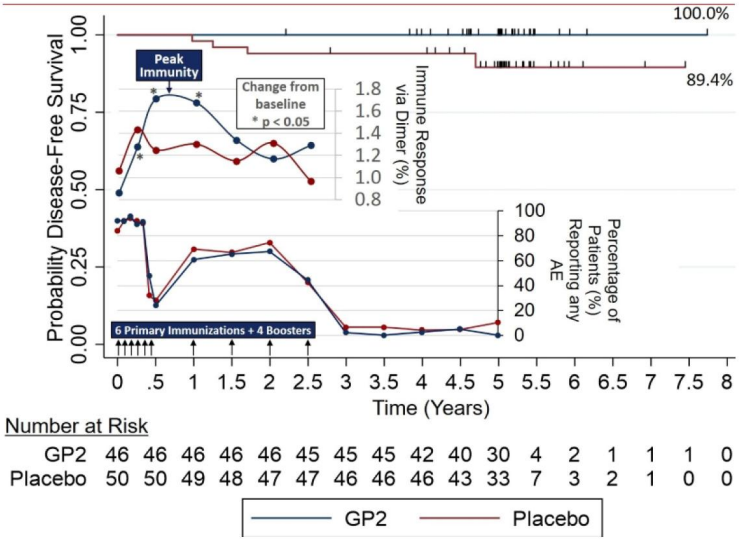
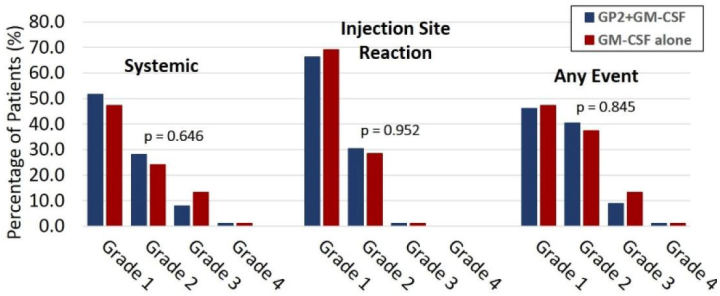


Figure 1 shows a time series of the GP2 immunotherapy injections, adverse events (AE), immune response, and 100% disease-free survival (0% recurrence rate) in HER2 positive breast cancer patients over median 5 years. This time series highlights that the 10 GP2 immunotherapy injections over the first 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.

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)
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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 (%)
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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.

GP2 Planned Phase III Trial:

Strategy – Conservatively Reproduce Phase IIb Trial in Larger Population

Greenwich LifeSciences

ASCO 2021 – Baylor Lead Site & Phase III Clinical Trial Design

American Society of Clinical Oncology, June 4-8, 2021

For Audio Recording, Please Visit: https://greenwichlifesciences.com/clinical-trials/

A prospective, randomized, multicenter, double-blinded, placebo-controlled phase III trial of the HER2/neu peptide GP2 + GM-CSF versus bacteriostatic saline/WFI placebo as adjuvant therapy after any trastuzumab-based therapy in HER2-positive women with operable breast cancer

Snehal S Patel[1], David B McWilliams[1], Christine T Fischette[1], Jaye Thompson[1], F Joseph Daugherty[1], C Kent Osborne[2] and Mothaffar F Rimawi[2].
[1]Greenwich LifeSciences, Stafford, TX; [2]Baylor College of Medicine, Houston, TX

Greenwich LifeSciences

Baylor College of Medicine
DAN L DUNCAN COMPREHENSIVE CANCER CENTER

BACKGROUND

GP2 is a biologic nine amino acid peptide of the HER2/neu protein delivered in combination with an FDA-approved immunoadjuvant, Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF, Sargramostim, Leukine), that stimulates an immune response targeting HER2/neu expressing cancers. In a prospective, randomized, single-blinded, placebo-controlled, multicenter Phase IIb clinical trial, no recurrences were observed in the HER2/neu positive adjuvant setting after median 5 years of follow-up, if the HLA 2+ patient received the 6 primary intradermal GP2 injections over the first 6 months ($p = 0.033$#) in a pre-specified subgroup analysis. Furthermore, the GP2 immunotherapy elicited a potent immune response measured by local skin tests and immunological assays.

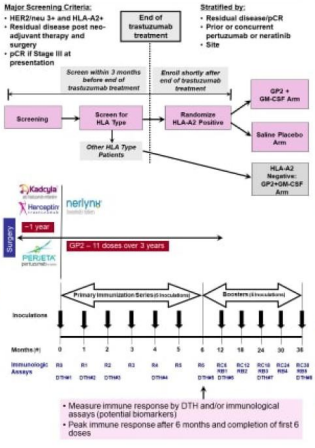
Of the 138 patients that have been treated with GP2 to date over 4 clinical trials, GP2 immunotherapy was well-tolerated and no serious adverse events were observed related to the GP2 immunotherapy.

This Phase III trial aims to reproduce the Phase IIb trial and will explore the use of GP2 + GM-CSF as adjuvant therapy to increase invasive disease-free survival in HER2/neu positive and HLA 2+ patients, post-surgery and following the first year of treatment with any trastuzumab-based therapy.

TRIAL DESIGN

This Phase III trial is a prospective, randomized, double-blinded, multi-center study. After 1 year of trastuzumab-based therapy or an approved biosimilar, 6 intradermal injections of GP2 + GM-CSF or placebo (Bacteriostatic Saline/WFI) will be administered for the primary immunization series over the first 6 months and 5 subsequent boosters will be administered over the next 2.5 years for a total of 11 injections over 3 years of treatment. The participant duration of the trial will be 3 years treatment plus 1 additional year follow-up for a total of 4 years following the first year of treatment with trastuzumab-based therapy. An interim analysis is planned, and patients will be stratified based on prior and current treatments.

SCHEMA



PATIENT POPULATION

The patient population is defined by these key eligibility criteria:

- HER2/neu positive and HLA-A2+
- Residual disease or High risk pCR (Stage III at presentation) post appropriate neo-adjuvant therapy
- Exclude Stage IV
- Completed at least 75% of planned trastuzumab therapy

TRIAL OBJECTIVES

1. To determine if GP2 therapy increases invasive disease-free survival (IDFS)
2. To assess the safety profile of GP2
3. To monitor immunologic responses to treatment and assess relationship to efficacy and safety

STUDY SIZE – INTERIM ANALYSIS

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

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FUNDING

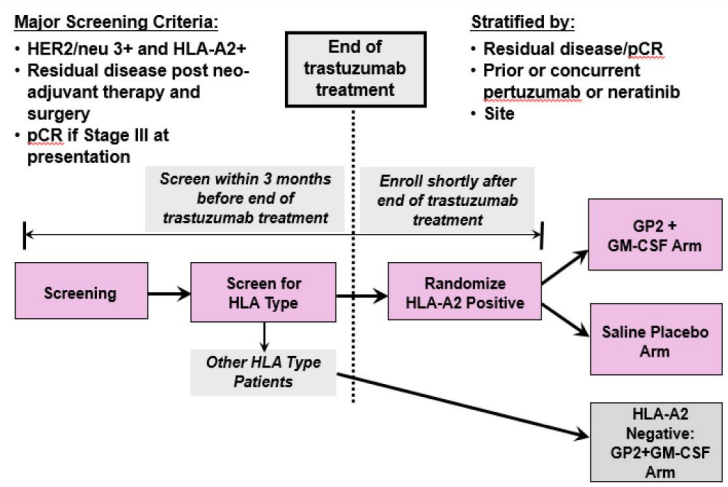
This trial is supported by Greenwich LifeSciences.

Abstract TPS604

Greenwich LifeSciences

ASCO 2021 – Phase III Trial Schema & Interim Analysis

Phase III Trial Schema



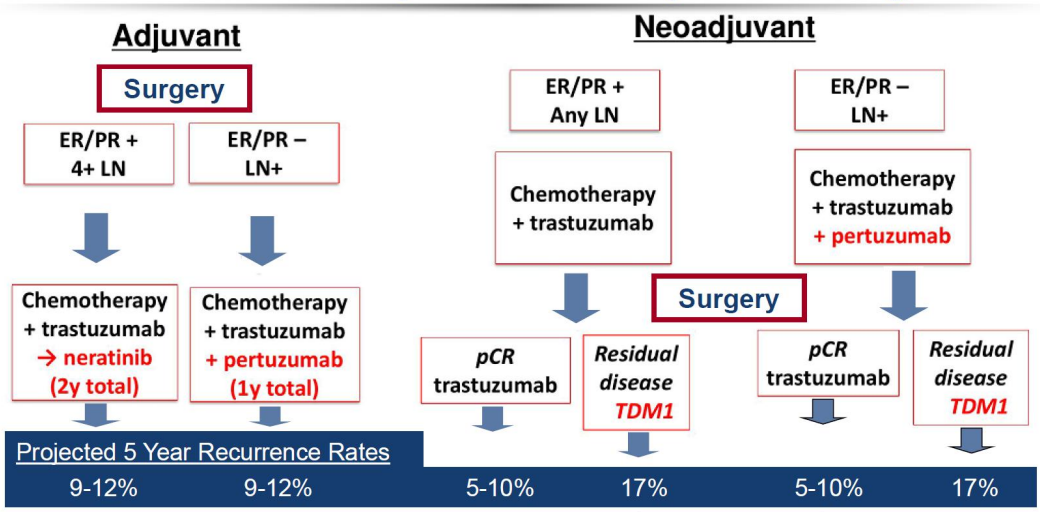
Interim Analysis Design

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)
- Plan to start trial in 2021 and enroll in 1.5 to 2 years
- Compare iDFS of GP2-treated versus placebo using standard of care

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

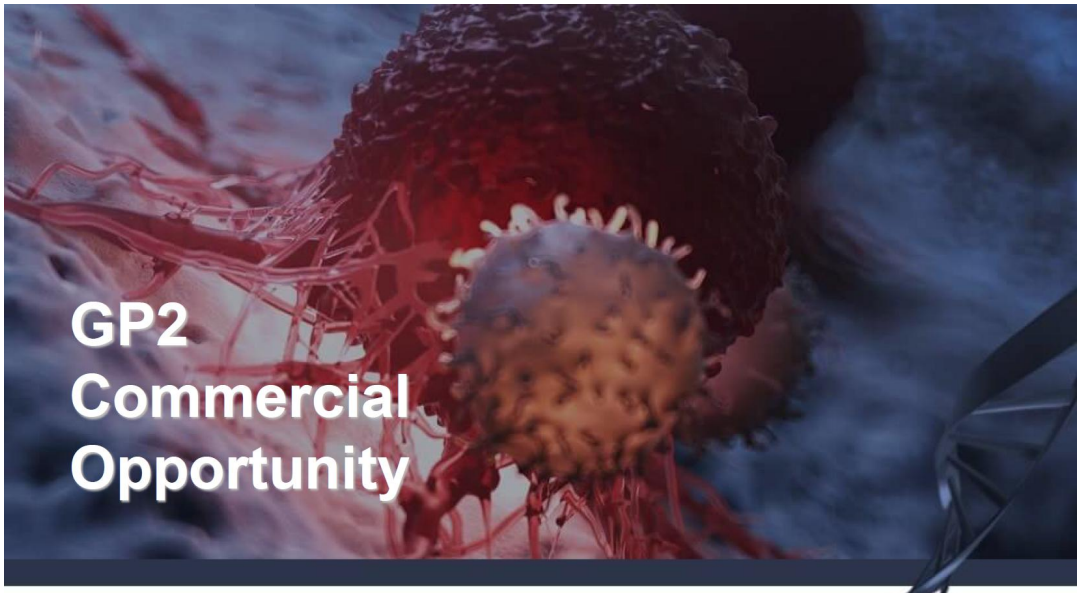
Target Population for Phase III Trial: Residual Disease & High Risk pCR

Annual recurrence rate = 3.0-3.4%

Annual recurrence rate design for Phase III trial = 2.4%

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
  - Commenced engineering scale-up run for commercial scale manufacturing
  - Phase III trial lot planned completion in 2021
  - 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 – 10-12 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 and additional patent term extensions upon approval of BLA

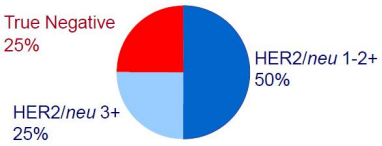


GP2 Commercial Opportunity

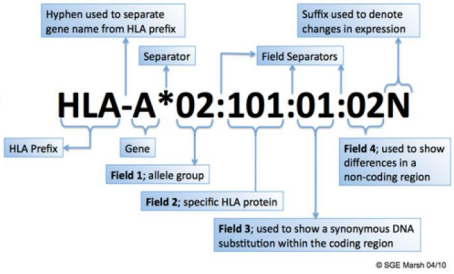
Greenwich LifeSciences

Potential Additional Indications of GP2 & Herceptin in Various Populations in Adjuvant 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 (additional 30%)
  - Human leukocyte antigen presents peptide from inside cancer cell to killer T-cells
  - HLA also presents injected peptide to create killer T-cells following intradermal injection



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 2019)**
- **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	

Multi $ Billion Revenue Potential

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

Approved on Y3 Post-Surgery Data

- 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
- 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.
- 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%).

Herceptin ADC 4:1

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**

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

Capitalization & Share Price Appreciation

- Raised approximately $36.5M from IPO & Follow-on in 2020
- Added to Russell 2000 on 6/28/21
- 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

As of 6/30/21	
Cash	$29.8m
Common Shares	12.9m
Warrants & Options	0.1m
Fully Diluted Shares	13.0m
Ownership (Tightly Held)	75-85%
Liabilities	$0.7m

Trading & Transaction Comparables

Trading Comparables

As of Market Close on 6/25/21

Company	Stock Symbol	Price	52 Wk Range	Avg Volume (3mo)	Market Cap	Comments
Late-Stage Breast Cancer / ImmunoOncology						
Greenwich LifeSciences	GLSI	$43.80	$3.26 - 158.07	422,126	$565M	Recently announced positive Phase II data
Seagen	SGEN	$157.18	$133.20 - 213.94	848,487	$28.525B	Recently announced positive Phase II data, tucatanib approval, Merck collaboration
G1 Therapeutics	GTHX	$23.98	$10.81 - 37.07	1.029M	$1.009B	Recently announced positive Phase II & III data
Macrogenics	MGNX	$27.17	$18.16 - 30.48	846,109	$1.631B	Recently announced positive Phase III data
Puma Biotechnology	PBYI	$9.63	$7.48 - 14.14	311,171	$389M	Pure play comp with Nerlynx not as effective and more toxicity than GP2

Transaction Comparables - Breast Cancer & Peptide Immunotherapy

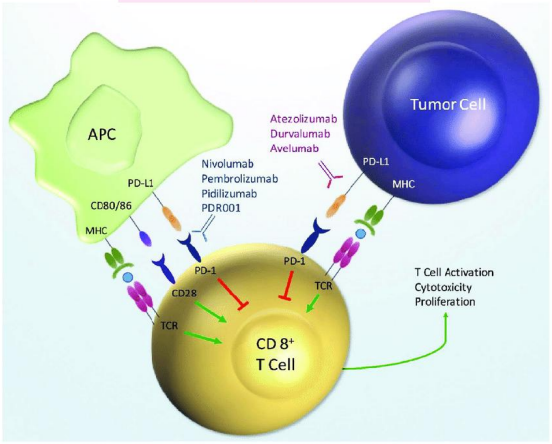
- September 14, 2020 – Gilead acquires Immunomedics for $21b for recently approved breast cancer drug
  - Acquires Trodelvy to treat metastatic triple-negative breast cancer
- September 16, 2020 – Merck partners with Seagen for up to $4.4b for 2 breast cancer drugs
  - Invests $1b equity & $725m upfront for breast cancer drug in development and limited Tukysa rights
- October 1, 2020 – Genentech (Roche) partners with Vaccibody for up to $715m
  - $200m upfront and near-term plus up to $515m in future milestones for neoantigen cancer vaccines
- August 9, 2021 – Seagen partners with China's RemeGen for up to $2.6b for HER2 targeted ADC
  - $200m upfront for ex-Asia rights. Seagen to commercialize rest of world, including Japan/Singapore.
- September 7, 2021 – Genentech (Roche) partners with Adaptimmune for up to $3.3b for T-cell therapy
  - $150m upfront & $150m over next 5 years, plus $3b in milestones

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

- Phase IIb trial: In HER2 3+ patients, 0% breast cancer recurrences post-surgery, if fully immunized, ($p = 0.0338$), peak immunity after 6 months, minimal to no side effects, median 5 years follow-up, randomized, placebo-controlled, multi-center (16 sites, 96 patients), study led by MD Anderson
- Conservative design of Phase III trial to reproduce Phase IIb results
- Planned Phase III Trial: Breast cancer post-surgery adjuvant/neoadjuvant setting, HER2/*neu* 3+, HLA-A2 patients starting in Y2 following Herceptin or Kadcyla
- Regulatory/Manufacturing - finalizing Phase III trial protocol, interim analysis added & CMC - Phase III lot near completion
- 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, as of 9/1/21, best performing biotech IPO of 307 IPOs since February 2019 – 661% return (BioPharmCatalyst)

Exhibit 99.2

November 9, 2021

Greenwich LifeSciences Provides Updated Corporate Presentation and Webcasts

STAFFORD, Texas--(Business Wire) - Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the "Company"), a clinical-stage biopharmaceutical company focused on the development of GP2, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery, today provides investors with its updated corporate presentation and recent webcasts.

A webcast of the Company's updated corporate presentation with comments by CEO Snehal Patel is available in the investor section of the Company's website here.

Mr. Patel commented, "We are very excited to be presenting the combined analysis of our five year Phase IIb data from our recently published posters on one timeline, and we expect more upcoming publications. Integrated analysis of efficacy, immune response, and safety data has attracted the interest of large institutions, including large pharma, regional pharma, and biotech institutional investors, whom we are presenting to at investor and international partnering conferences. We have been discussing possible licensing of GP2, new investment banking partners, collaboration in our Phase III clinical trial, commercial manufacturing, expansion of our pipeline, expansion of our clinical trials in Europe, and initiation of additional GP2 Phase II/III trials."

Additional webcasts of Mr. Patel's participation on a Benzinga cancer panel and a TD Ameritrade interview can be viewed at the links below:

On September 30, 2021, Mr. Patel participated in a live panel discussion at the Benzinga Healthcare Small-Cap Conference entitled: Immuno-Oncology - Harnessing the Human Body's Power to Battle Cancer. A webcast of the panel discussion can be seen here with Mr. Patel speaking at the time points 2:15, 18:03, and 34:00.

On July 20, 2021, Mr. Patel appeared as a featured guest in a live interview on TD Ameritrade Network's *The Watch List* with host Nicole Petallides. A webcast of the interview can be seen here.

About Breast Cancer and HER2/*neu* Positivity

One in eight U.S. women will develop invasive breast cancer over her lifetime, with approximately 282,000 new breast cancer patients and 3.8 million breast cancer survivors in 2021. HER2/*neu* (human epidermal growth factor receptor 2) protein is a cell surface receptor protein that is expressed in a variety of common cancers, including in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or over-expressor) levels.

About Greenwich LifeSciences, Inc.

Greenwich LifeSciences is a clinical-stage biopharmaceutical company focused on the development of GP2, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery. GP2 is a 9 amino acid transmembrane peptide of the HER2/*neu* protein. In a randomized, single-blinded, placebo-controlled, multi-center (16 sites led by MD Anderson Cancer Center) Phase IIb clinical trial, no recurrences were observed in the HER2/*neu* 3+ adjuvant setting after median 5 years of follow-up, if the patient received the 6 primary intradermal injections over the first 6 months ($p = 0.0338$). Of the 138 patients that have been treated with GP2 to date over 4 clinical trials, GP2 treatment was well tolerated and no serious adverse events were observed related to GP2 immunotherapy. Greenwich LifeSciences is planning to commence a Phase III clinical trial using a similar treatment regime as the Phase IIb clinical trial. For more information on Greenwich LifeSciences, please visit the Company's website at www.greenwichlifesciences.com and follow the Company's Twitter at https://twitter.com/GreenwichLS.

About GP2 Immunotherapy Immune Response

As previously reported, GP2 immunotherapy generated GP2-specific immune responses, leading to no metastatic breast cancer recurrence in the HER2/*neu* 3+ population in the Phase IIb clinical trial, thus supporting GP2's mechanism of action. Statistically significant peak immunity was reached after 6 months of GP2 treatment, as measured in both the Dimer Binding Assay and the DTH skin test. HER2/*neu* 3+ population immune response was similar to the HER2/*neu* 1-2+ population immune response, suggesting the potential to treat the HER2/*neu* 1-2+ population (including triple negative breast cancer) with GP2 immunotherapy in combination with trastuzumab (Herceptin) based products and other clinically active agents. The broad based immune response suggests the potential for GP2 to treat other HER2/*neu* 1-3+ expressing cancers. For more information on GP2 immune response and clinical data, please visit the Company's clinical trial tab at https://greenwichlifesciences.com/clinical-trials/.

Forward-Looking Statement Disclaimer

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Greenwich LifeSciences Inc.'s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including statements regarding the intended use of net proceeds from the public offering; consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the final prospectus related to the public offering filed with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Greenwich LifeSciences, Inc. undertakes no duty to update such information except as required under applicable law.

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