

GREENWICH LIFESCIENCES

Planned GP2 Phase III Clinical Trial

A Breakthrough Targeted Immunotherapy to Prevent Breast Cancer Recurrences

NASDAQ: GLSI

Snehal Patel, CEO
David McWilliams, Chairman



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Filed pursuant to Rule 433 of the Securities Act of 1933
Issuer Free Writing Prospectus dated December 16, 2020
Relating to the Preliminary Prospectus dated December 15, 2020
Registration Statement File No. 333-251366

Image: T-cells targeting cancer cell

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Offering Details

ISSUER	Greenwich LifeSciences, Inc.
TICKER/EXCHANGE	GLSI / NASDAQ Capital Markets
OFFERING TYPE	Follow-On
GROSS PROCEEDS	\$22,000,000 Base Deal (15% over-allotment option)
USE OF PROCEEDS	(i) Enroll and treat patients in Phase III clinical trial; and (ii) Working Capital and General Corporate Purposes



GP2 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:** No recurrences, if fully immunized, versus 11% placebo recurrence rate in 96 patients, with minimal to no side effects, no SAEs ($p = 0.0338$)
 - 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 - final revisions to the Phase III trial protocol are under way
- **Manufacturing:** Straight forward, completing scale-up, started Phase III lot
- **Multiple Phase II Trial 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":** Closed IPO on September 29, 2020



Breast Cancer – Still a Substantial Unmet Need

- **Unmet Need is to address the 50% of recurring patients who do not respond to Herceptin or Kadcylla – 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:** Kadcylla was just approved for use in patients with residual disease determined via pCR at time of surgery. Kadcylla 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.

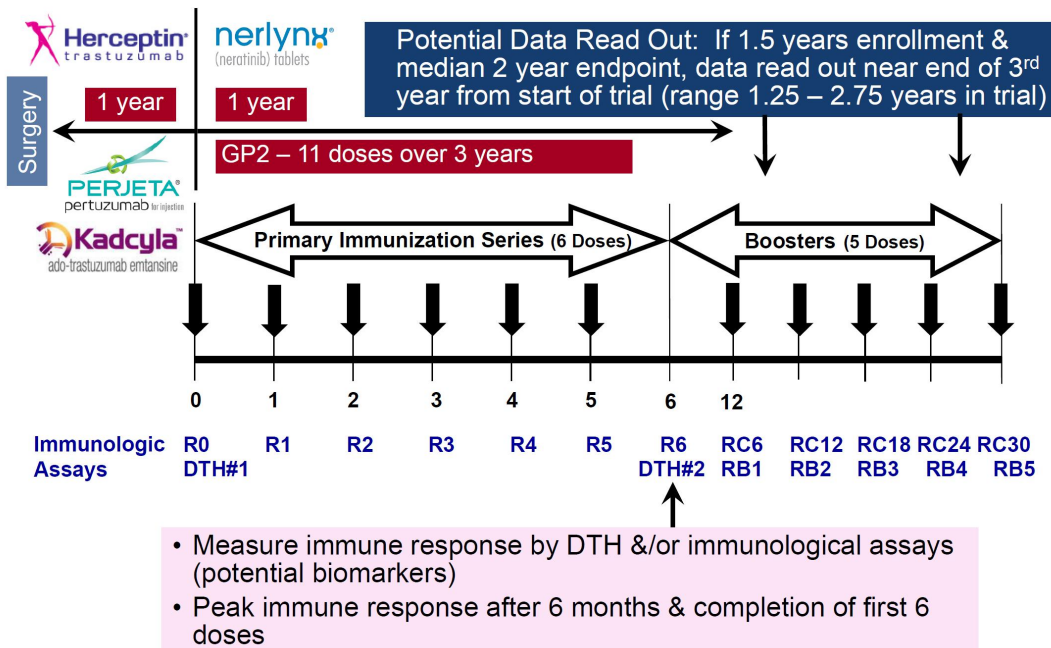
In the initial GP2 indication, approximately 17,000 new patients could be treated per year, saving up to 1,500 to 2,000 lives per year.



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

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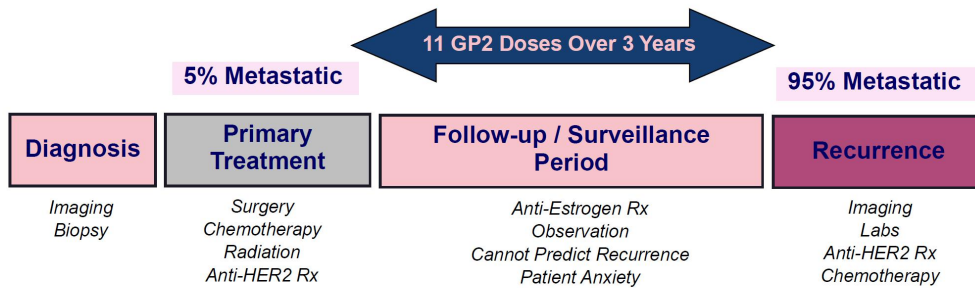
GP2 Phase III Clinical Trial Dosing



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- As only injection site reactions were observed (which speaks to the immunogenicity of GP2) and no SAEs, 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 to substantially
- GP2 can be the treatment that will naturally overlap with or follow Herceptin, Kadcylla, or Enhertu or any of the other Herceptin derivatives being developed



SABCS 2020 – GP2 5 Year Data Published

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

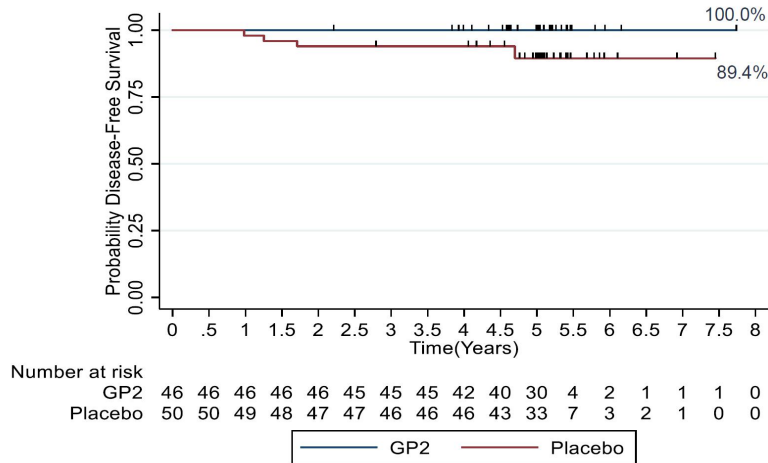
Characteristic	HER2 3+			HER2 1-2+		
	GP2 (n = 46)	Placebo (n = 50)	p value ¹	GP2 (n = 35)	Placebo (n = 37)	p value ¹
Age (median, [min, max])	50.5 (26.9-72.3)	52.1 (33.7-72.1)	0.4011	50.8 (36.7-76.7)	49.9 (26.3-89.2)	0.8146
T Stage						
T0/Is	2 (4.4%)	1 (2.0%)	0.874	0 (0.0%)	0 (0.0%)	0.654
T1	23 (50.0%)	28 (56.0%)		14 (40.0%)	11 (29.7%)	
T2	17 (37.0%)	14 (28.0%)		14 (40.0%)	17 (46.0%)	
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 (48.9%)	19 (51.3%)	
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%)	

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



SABCS 2020 – GP2 5 Year Data Published

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.



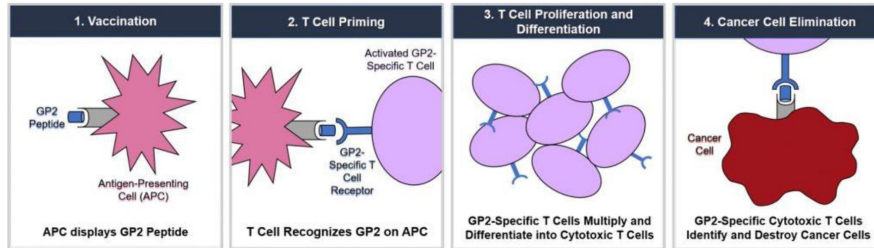
GP2 Product Description & Mechanism of Action

- 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 All GP2 Trials – 3 Phase I & 1 Phase IIb (Total N=138 Patients Treated to Date with No SAEs)

Protocol No./ Protocol Title	Status
Protocol No. C.2007.098/IRBNet# 363083 <ul style="list-style-type: none"> • Prospective, Randomized, Single-Blinded, Multi-Center Phase II Trial of the HER2/<i>neu</i> Peptide GP2 + GM-CSF Vaccine versus GM-CSF Alone in HLA-A2+ Node-Positive and High-Risk Node-Negative Breast Cancer Patients to Prevent Recurrence • 89 patients treated with GP2 + GM-CSF, 91 placebo patients treated with GM-CSF 	Trial Completed
Protocol No. C.2008.146/ IRBNet# 363196 <ul style="list-style-type: none"> • Phase Ib Trial of Combination Immunotherapy with HER2/<i>neu</i> Peptide GP2 + GM-CSF Vaccine and Trastuzumab in Breast Cancer Patients • 17 patients treated with GP2 + GM-CSF + trastuzumab 	Trial Completed
Conducted at Brooke Army Medical Center and Mary Crowley Medical Research Center <ul style="list-style-type: none"> • Phase I Safety Trial of the GP2 + GM-CSF Vaccine in Combination with the Helper Peptide AE37 + GM-CSF Vaccine • 14 patients treated with GP2 + AE37 + GM-CSF 	Trial Completed
Protocol No. 04-20017 / IRBNet ID 20307 <ul style="list-style-type: none"> • Phase Ib Trial of HER2/<i>neu</i> Peptide (GP2) Vaccine in Breast Cancer Patients • 18 patients treated with GP2 + GM-CSF 	Trial Completed

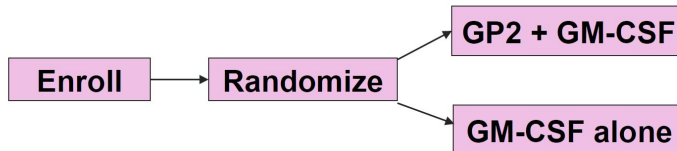


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Design of Phase IIb Clinical Trial

- Prospective, randomized, single-blinded, placebo-controlled phase IIb clinical trial of GP2 + GM-CSF or GM-CSF alone in 180 intent to treat HER2/neu 1-3+, HLA-A2 patients at 16 civilian/military clinical sites, led by MD Anderson
- High-risk breast cancer patients (Node Positive, High Risk Node Negative) who were disease-free and immunocompetent after having completed standard of care therapy
- A recurrence is defined as either a pathologically confirmed recurrence or a new radiographic finding during standard of care follow-up



Primary Objective

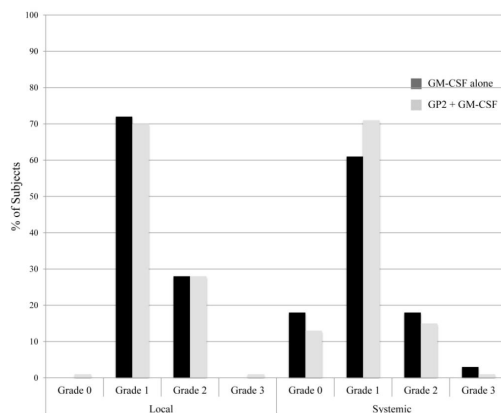
- Determine if GP2+GM-CSF treatment reduces recurrence rates vs. GM-CSF alone

Secondary Objective

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

Phase IIb Clinical Data – No SAEs

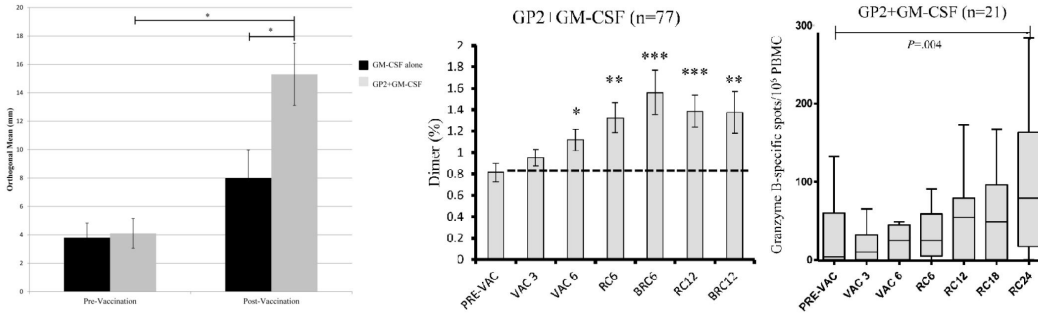
- Maximum local and systemic toxicities were primarily grade 1 and grade 2
- Toxicities ranged from redness at injection site to flu-like symptoms and can be largely attributed to GM-CSF, not GP2



Toxicity: The maximum local and systemic toxicity experienced by patients administered the GP2+GM-CSF vaccine were comparable to those experienced by patients receiving GM-CSF alone. For patients receiving GP2 + GM-CSF, maximum local toxicities experienced during the PVS were grade 1 (70%), grade 2 (28%), or grade 3 (1%). The most common toxicities included erythema, induration and pruritis; the grade 3 toxicity was induration. Maximum systemic toxicities were grade 0 (13%), grade 1 (71%), grade 2 (15%), or grade 3 (1%). The most common systemic toxicities included fatigue, headache, and myalgias; the grade 3 toxicity was a diffuse maculopapular rash. The toxicities were comparable for patients receiving GM-CSF only, with maximum local toxicities being grade 1 (75%) or grade 2 (25%); and maximum systemic toxicities being grade 0 (21%), grade 1 (60%), grade 2 (15%), or grade 3 (3%). The grade 3 systemic toxicities in this group included diffuse urticarial reactions, syncope and extremity pain.

No SAEs. Primarily injection site reactions which are caused by GM-CSF & can be mitigated by reducing GM-CSF dose (and then GP2, if necessary)

- Immune response was observed peaking after 6 months compared to baseline, measured by Delayed Type Hypersensitivity (DTH skin test using GP2) and immunological assay. DTH response rate for treated patients is very high. Orthogonal mean baseline vs 6 months: $4.1 \pm 1.1\text{mm}$ versus $15.3 \pm 2.2\text{mm}$ (\pm standard error)
- Boosters administered every 6 months to sustain immunity
- Per treatment: 96 HER2/neu 3+, HLA-A2 patients - No recurrences if fully immunized at 6 months following 1st year of Herceptin treatment => target population for Phase III trial
- Per treatment: 72 HER2/neu 1-2+, HLA-A2 patients - No reduction in recurrence rate, but Herceptin was not administered to these patients => pursue in future with Herceptin combination therapy

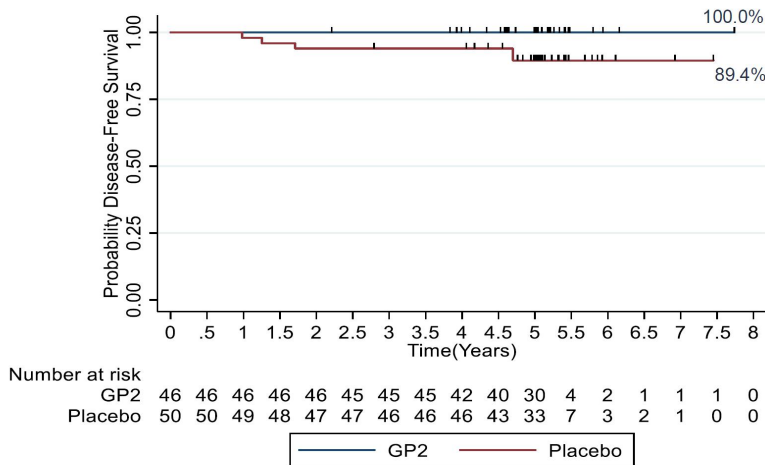


Immune response peaks after 6 months of 6 doses, thereafter reducing recurrence rates from 11% to 0% at median 5 years follow-up



SABCS 2020 – GP2 5 Year Data Published

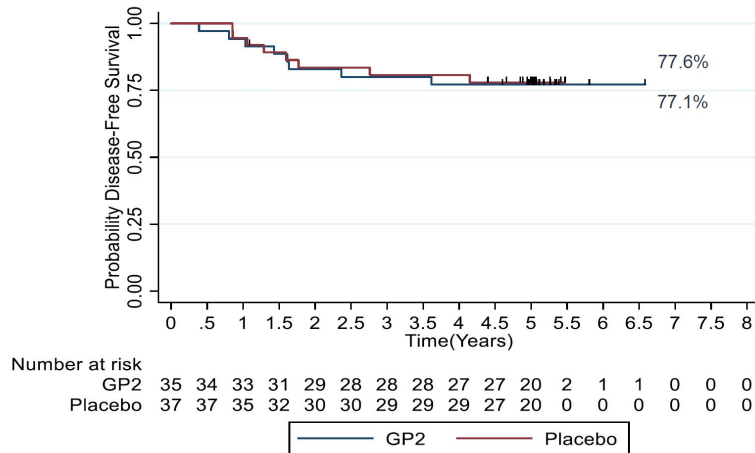
Figure 1: HER2 3+ Subjects Who Completed PIS Following Trastuzumab



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 ($p = 0.9142$).



Phase III Clinical Trial – Protocol Reviewed by FDA

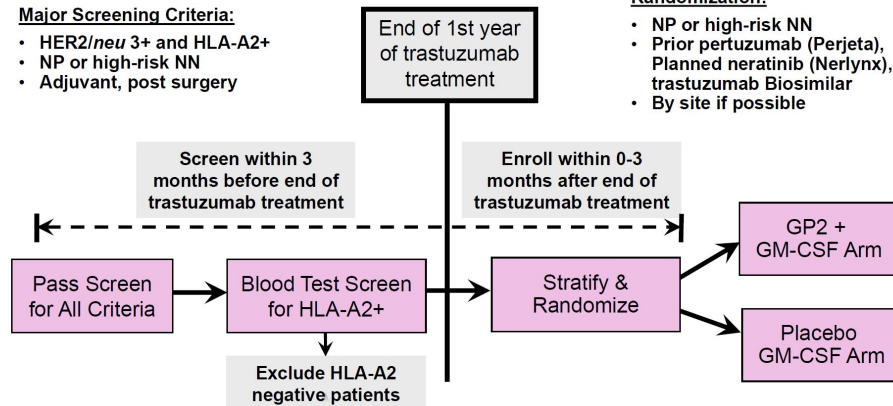
Title: “Study Evaluating The Reduction Of Recurrences Using HER2/neu Peptide GP2 + GM-CSF Vaccine After Adjuvant Trastuzumab In HLA-A2-Positive, HER2-Positive (3+) Women With Operable Breast Cancer”

Major Screening Criteria:

- HER2/neu 3+ and HLA-A2+
- NP or high-risk NN
- Adjuvant, post surgery

Randomization:

- NP or high-risk NN
- Prior pertuzumab (Perjeta), Planned neratinib (Nerlynx), trastuzumab Biosimilar
- By site if possible



- Plan to start trial in 2021
- Enrollment period: 1.5 to 2 yrs
- Primary endpoint: Compare recurrence rate of GP2-treated vs. placebo at median 2, 3, 4, & 5 years follow-up using standard of care



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Manufacturing / Regulatory / IP

- GP2 manufactured by straightforward amino acid chemistry
 - Manufactured by FDA-approved commercial facility with multiple back-up facilities
 - Detailed CMC plan reviewed by FDA
 - Commenced engineering scale-up run for commercial scale manufacturing
 - Phase III trial lot commenced in 2019
 - 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



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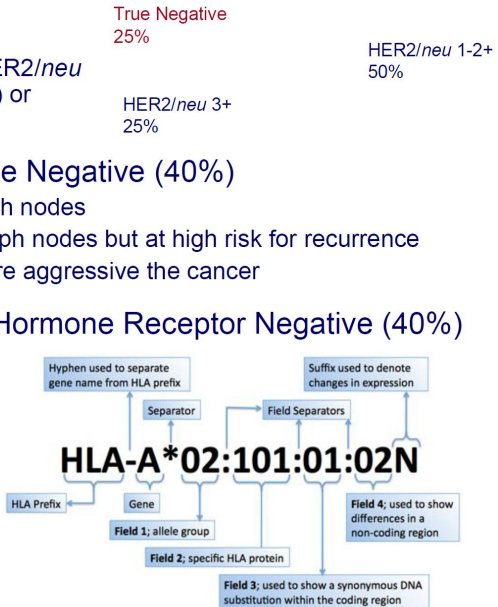


GP2 Commercial Opportunity



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 fluorescence 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



- 1 in 8 U.S. women (12.4%) will develop invasive breast cancer over her lifetime, with 266k new breast cancer patients per year in 2018
- 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 (3.1m as of 2018)
- 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 = 3.1m current breast cancer survivors and 266k 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	33,250	16,750 – 79,800
Adjuvant Patients Treated per Year (est. from sales)	27,000 – 40,000	
Estimated Adjuvant Setting US Revenue (\$ billions)		
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)		
Adjuvant Setting	\$2-3	
Metastatic Breast Cancer	\$4-5	



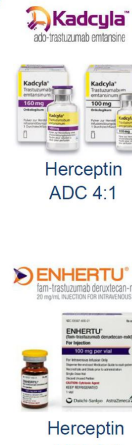


Approved on Y3 Post-Surgery Data

PERJETA
pertuzumab injection

nerlynx
(neratinib) tablets

- 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%).



Kadcyla
ado-trastuzumab emtansine

Herceptin ADC 4:1

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

Herceptin ADC 8:1

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



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
- Eric Rothe – Board & Founder of GLSI
- Ken Hallock – Board & Major Investor



Capitalization (as of 9/30/20)

CASH	\$6.2m
COMMON SHARES	11,970,185
WARRANTS AND OPTIONS	100,870
FULLY DILUTED SHARES	12,071,055
OWNERSHIP (TIGHTLY HELD BY INSIDERS)	80-90%
LIABILITIES	\$1.6m



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

- **Phase IIb trial:** No breast cancer recurrences post-surgery, if fully immunized, ($p = 0.0338$), with minimal to no side effects, at 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 Kadcyła
- FDA-reviewed Phase III trial protocol & CMC, Initiated scale-up manufacturing for Phase III trial, & Finalizing CRO selection/budget
- **Multiple Phase II trial opportunities to expand breast cancer 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”:** Closed IPO on September 29, 2020



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 Greenwich
LifeSciences
NASDAQ: GLSI

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