December 9, 2020

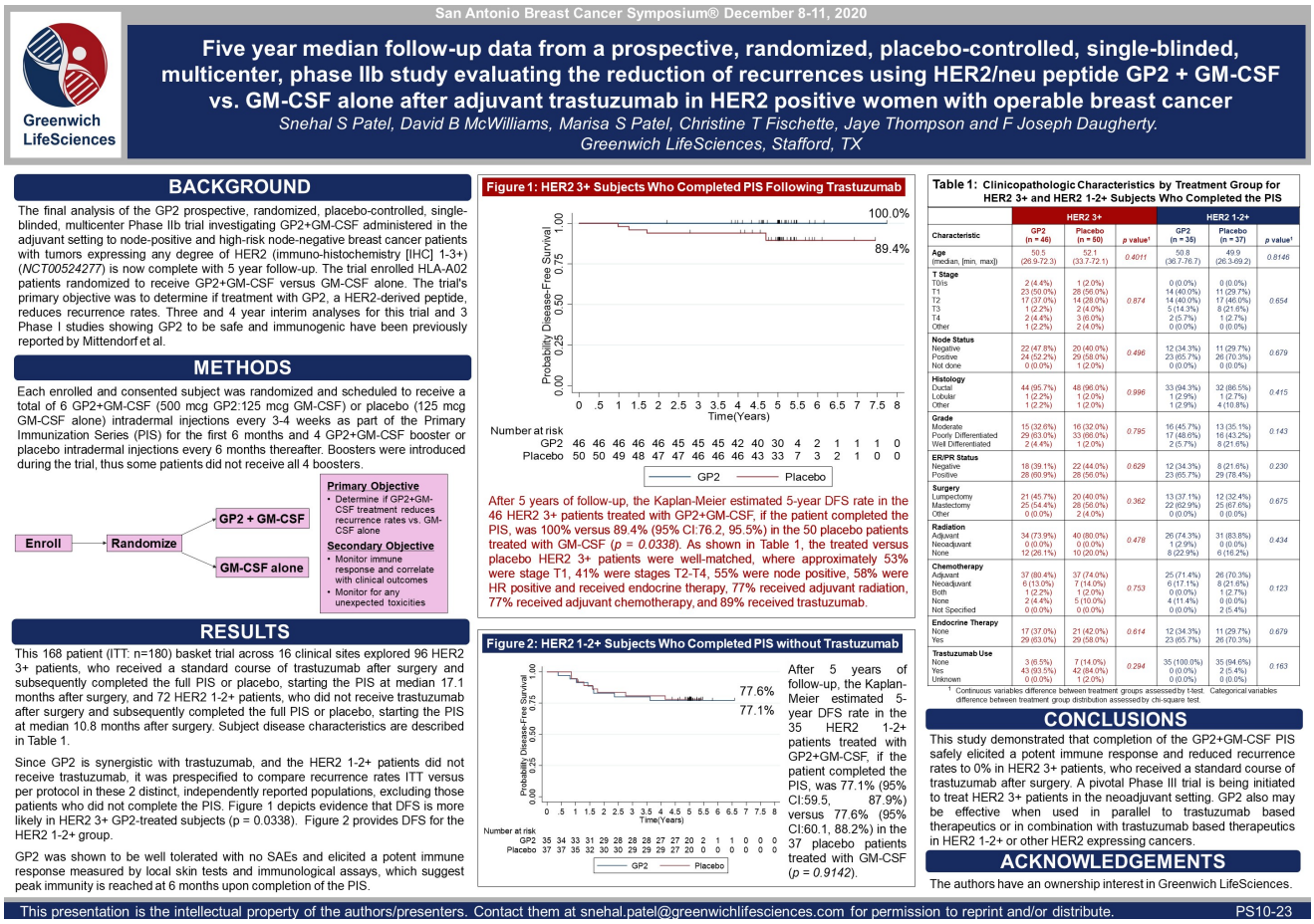
Greenwich LifeSciences Announces Poster Presentation of Five Year Data for GP2 Phase IIb Clinical Trial, Showing 0% Recurrence of Breast Cancer

– Poster for GP2 Phase IIb clinical trial final efficacy analysis was presented during the 2020 San Antonio Breast Cancer Symposium (SABCS) today

– Phase IIb clinical trial was a prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites) trial led by MD Anderson Cancer Center

– Kaplan Meier analysis of disease free survival for patients treated with GP2 immunotherapy shows 100% survival (0% breast cancer recurrences, $p = 0.0338$) following surgery and Herceptin treatment over median 5 years of follow-up

– Company now preparing to enter a Phase III clinical trial to treat a similar population of moderate to severe (high risk T1, T2-T4) breast cancer patients



Poster PS10-23: San Antonio Breast Cancer Symposium 2020 Poster Presentation of GP2 Median 5 Year Top-Line Data (Graphic: Business Wire)

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 announced the publication of a poster for the GP2 Phase IIb clinical trial final efficacy analysis at the San Antonio Breast Cancer Symposium in a virtual format. The CEO of Greenwich LifeSciences, Snehal Patel, also recorded an audio track providing an overview. The full poster with figures, tables, and audio can be accessed or downloaded here on the Company website, as well as on the conference website by attendees.

The poster presents the final 5 year follow-up disease-free survival curves evaluating the reduction of breast cancer recurrences for both HER2/*neu* 3+ (Figure 1) and HER2/*neu* 1-2+ (Figure 2) patient populations, including the demographics (Table 1) for stage of cancer, hormone receptor status, node status, and prior treatment with chemotherapy, radiation, endocrine therapy, or trastuzumab (Herceptin).

Mr. Patel commented, “The poster presented at the SABCS is important because the Kaplan Meier survival curves and demographic data further validate our promising HER2 3+ Phase IIb data and support our plan to commence a Phase III trial in 2021. Recurring breast cancer affects 1 in 8 women. Approximately 50% of women with recurring breast cancer do not respond to Herceptin or Kadcyla, resulting in metastatic breast cancer and a poor prognosis.

Approximately 80-85% of metastatic breast cancer patients do not survive. By addressing this unmet need, GP2 may reach a potential market exceeding $5 billion."

The conclusions of the poster are as follows:

– The trial met all of its clinical endpoints for HER2/*neu* 3+ patients, concluding that the first 6 intradermal injections of GP2+GM-CSF safely elicited a potent immune response and reduced recurrence rates to 0% in HER2/*neu* 3+ patients, who received a standard course of Herceptin after surgery. This reduction of recurrence rate was maintained over the gold standard of 5 years of follow-up. A pivotal Phase III trial is being initiated to treat HER2/*neu* 3+ patients in the neoadjuvant setting.

– GP2 may also be effective when administered in combination with Herceptin based therapeutics in HER2/*neu* 1-2+ patient populations or other HER2/*neu* expressing cancers.

Excerpts of the poster are below:

Poster PS10-23: San Antonio Breast Cancer Symposium Poster Presentation of Median 5 Year Top-Line Data

The median 5 year top-line data described below was presented at the San Antonio Breast Cancer Symposium in a poster on December 9, 2020, entitled "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."

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.

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.

This 168 patient (Intent to Treat, "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 of the poster.

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 of the poster depicts evidence that disease free survival ("DFS") is more likely in HER2 3+ GP2-treated subjects. 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 hormone receptor positive and received endocrine therapy, 77% received adjuvant radiation, 77% received adjuvant chemotherapy, and 89% received trastuzumab.

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.

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

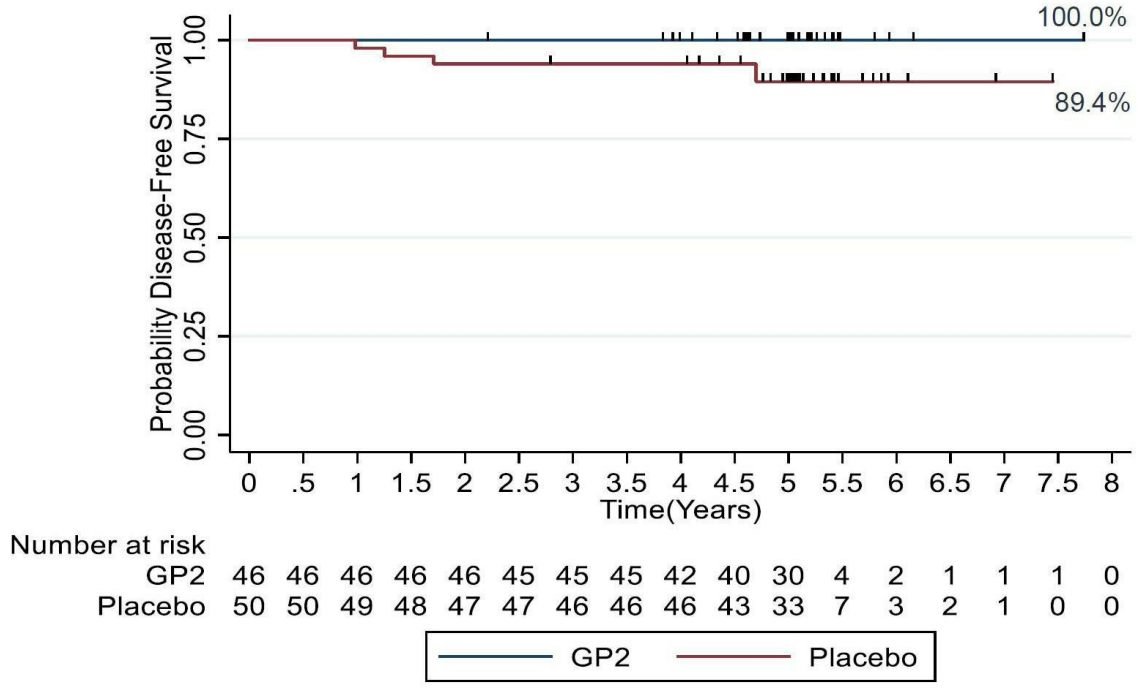
	HER2 3+			HER2 1-2+		
Characteristic	**GP2 (n = 46)**	**Placebo (n = 50)**	***p* value[1]**	**GP2 (n = 35)**	**Placebo (n = 37)**	***p* value[1]**
Age (median, [min, max])	50.5 (26.9-72.3)	52.1 (33.7-72.1)	*0.4011*	50.8 (36.7-76.7)	49.9 (26.3-69.2)	*0.8146*
T Stage						
T0/is	2 (4.4%)	1 (2.0%)		0 (0.0%)	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%)	

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

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 hormone receptor positive and received endocrine therapy, 77% received adjuvant radiation, 77% received adjuvant chemotherapy, and 89% received trastuzumab. Primary Immunization Series (PIS) is the first 6 GP2+GM-CSF intradermal injections over the first 6 months. (Graphic: Business Wire)

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



As shown in Figure 1, 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). Primary Immunization Series (PIS) is the first 6 GP2+GM-CSF intradermal injections over the first 6 months. (Graphic: Business

Wire)

About SABCS

The 43rd annual SABCS has grown to be the industry's premier breast cancer conference for basic, translational, and clinical cancer research professionals. It is well-known for presenting the latest breast cancer data from all over the world. More than 7,500 health care professionals from more than 90 countries attend annually. Baylor College of Medicine became a joint sponsor of SABCS in 2005. The Cancer Therapy & Research Center at UT Health Science Center San Antonio and American Association for Cancer Research began collaborations with SABCS in 2007. For more information, please visit the conference website at: https://www.sabcs.org/

About Breast Cancer and HER2/*neu* Positivity

One in eight U.S. women will develop invasive breast cancer over her lifetime, with approximately 266,000 new breast cancer patients and 3.1 million breast cancer survivors in 2018. 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: www.greenwichlifesciences.com

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. 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 Securities and Exchange Commission. 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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