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Greenwich LifeSciences Presents Phase IIb Data, Published at AACR 2022, Further Supporting the Role of GP2 in Preventing Metastatic Breast Cancer

STAFFORD, Texas--(BUSINESS WIRE)-- Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the "Company"), a clinical-stage biopharmaceutical company focused on the development of GLSI-100, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery, today announced the following:

- Company management presented 2 Phase IIb clinical trial posters at the American Association for Cancer Research (AACR) Annual Meeting 2022, which was held from April 8-13, 2022 in New Orleans, Louisiana
- Both abstracts can be viewed below, and both posters, CT166 and CT161, can be accessed or downloaded from the Clinical Trials tab of the Company website at: https://greenwichlifesciences.com/clinical-trials/
- Abstract and poster CT166 demonstrated that GLSI-100 safely elicited a potent immune response, as evidenced by injection site reactions that correlate to and may serve as a complement to other immune response tests. The trastuzumab treated HER2 positive breast cancer patients appeared to be in a reduced immune state that was reversed with the addition of GP2, resulting in a significantly increased immune response that may protect against future metastatic breast cancer recurrence.
- Abstract and poster CT161 demonstrated that GP2 may be a natural antigen that is present before any GP2 treatment, suggesting that GP2 is a relevant target for T cell immunotherapy. In addition, a GP2 immune response prior to any GP2 treatment may help in predicting the probability and timing of breast cancer recurrence.

AACR Abstract CT166:

Title: Injection site reactions correlate to delayed type hypersensitivity tests and suggest that GP2 reverses immune suppression of trastuzumab-treated HER2 positive patients in a phase IIb study evaluating HER2/neu peptide GP2 (GLSI-100) vs. GM-CSF after adjuvant trastuzumab in HER2 positive women with breast cancer

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Greenwich LifeSciences, Stafford, TX

Background: Injection site reactions and Delayed Type Hypersensitivity (DTH) tests in the randomized, active-controlled, single-blinded, multicenter Phase IIb trial of GLSI-100

(GP2+GM-CSF) administered in the adjuvant setting to node-positive and high-risk node-negative breast cancer patients with tumors expressing HER2 have been analyzed. The trial enrolled HLA-A*02 patients randomized to receive GLSI-100 versus GM-CSF alone.

Methods: Patients were randomized and received GLSI-100 (500 mcg GP2+ 125 mcg GM-CSF) or control (GM-CSF) via 6 intradermal injections every 3-4 weeks for the first 6 months and 4 booster injections every 6 months. The magnitude of injection site reactions, which occurred in almost all patients, were assessed for the 10 doses administered by measuring the largest perpendicular diameters and the resulting orthogonal mean. DTH reactions were assessed in a similar manner at baseline and 6 months and have been previously reported.

Results: The study enrolled 180 patients who were HER2 3+ positive and low HER2 expressors (1-2+). After 5 years of follow-up, the Kaplan-Meier estimated 5-year DFS rate in the 46 HER2 3+ patients treated with GLSI-100, if completing the PIS, was 100% versus 89.4% (95% CI:76.2, 95.5%) in the 50 patients treated with GM-CSF ($p = 0.0338$). DTH reactions at baseline and 6 months were consistently correlated with injection site reactions suggesting that injection site reactions may be interchangeable with immune response data (baseline $\rho=0.6$, $p<0.001$; 6mo $\rho=0.4$, $p=0.009$). After a single dose, the median orthogonal mean induration was 7.8mm for GM-CSF patients and 34.0mm for GLSI-100 patients ($p = 0.0036$). Injection site reactions increased to 78mm after the 4^{th} injection but remained over 50mm for the duration of the injection series for those treated with GLSI-100. The magnitude of injection site reactions for patients treated with GLSI-100 was similar across HER2 status. However, HER2 3+ control patients had significantly smaller reactions to GM-CSF than HER2 1-2+ control patients with an average of 43.1mm difference over all 10 doses. Trastuzumab treated HER2 3+ control patients appeared to be in a suppressed immune state that reversed by adding GP2 treatment, increasing injection site reactions by an average of 39.2mm over all 10 doses (treatment and the interaction of HER2 status and treatment were statistically significant).

Conclusions: This study demonstrated that GLSI-100 safely elicited a potent immune response, as evidenced by injection site reactions that correlate to and may serve as a complement to immune response data such as DTH. The lower immune response of the trastuzumab treated HER2 positive control population, not evidenced in the low HER2 expressors who did not receive trastuzumab, suggests a reduced immune state potentially related to prior trastuzumab exposure which is reversed with the addition of GP2 and warrants further research.

AACR Abstract CT161:

Title: GP2 immune response a predictor of recurrence in a phase IIb study evaluating HER2/neu peptide GP2 (GLSI-100) vs. GM-CSF alone after adjuvant trastuzumab in HER2 positive women with breast cancer

Snehal S Patel, David B McWilliams, Mira S Patel, Jaye Thompson and F Joseph Daugherty.

Greenwich LifeSciences, Stafford, TX

Background: Delayed type hypersensitivity (DTH) skin tests to GP2 in the randomized, active-controlled, single-blinded, multicenter Phase IIb trial investigating GLSI-100

(GP2+GM-CSF) administered in the adjuvant setting to node-positive and high-risk node-negative breast cancer patients with tumors expressing HER2 have been analyzed. The trial enrolled HLA-A*02 patients randomized to receive GLSI-100 versus GM-CSF alone.

Methods: Patients were randomized and received GLSI-100 (500 mcg GP2: 125 mcg GM-CSF) or control (GM-CSF only) via 6 intradermal injections every 3-4 weeks as part of the Primary Immunization Series (PIS) for 6 months and 4 booster injections every 6 months thereafter. GP2 DTH skin tests were placed at baseline and after the 6^{th} dose. After 48-72 hours, the largest perpendicular diameters of induration were measured and the orthogonal mean was calculated. Induration of over 5mm was considered a positive response.

Results: The study enrolled 180 patients with both HER2 3+ positive and low HER2 expressors (1-2+). After 5 years of follow-up, the Kaplan-Meier estimated 5-year DFS rate in the 46 HER2 3+ patients treated with GLSI-100, 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 ($p = 0.0338$). Previous publications have reported the increase in GP2 DTH response reported among patients after treatment with GLSI-100 and the positive DTH responses to GP2 at baseline, where 22.8% (33/145) of patients reacted to GP2 at baseline with induration larger than 5mm. It was also previously reported that in the subgroup of subjects with recurrence, 36.4% (8/22) had a positive baseline DTH. Further analysis of all HER2 positive and HER2 low patients has shown that a KM log-rank test found a borderline effect ($p = 0.0956$) of baseline DTH status. At year 4, 88% of all patients without a positive baseline GP2 DTH remained disease-free. The patients with a positive baseline GP2 DTH recurred 3.5 years earlier reaching a similar survival probability of 88% at 6 months. In addition, the proportion of subjects recurring at any time amongst those with a positive baseline GP2 DTH response was 24.2% (8/33) compared to 12.5% (14/112) recurring with a negative baseline response ($p = 0.0984$) suggesting a positive baseline GP2 DTH is associated with recurrence.

Conclusions: The probability of recurrence is increased in subjects with a positive baseline GP2 DTH and recurrence is likely to occur years sooner than those without a positive GP2 DTH at baseline. Further studies assessing the prognostic value of GP2 immune response at baseline are planned, which may include additional measures of GP2 immune response and sequencing and identification of T cell profiles associated with residual disease, impending recurrence, or prior treatments.

About the AACR Annual Meeting 2022

The AACR is the first and largest cancer research organization dedicated to accelerating the conquest of cancer and has more than 48,000 members residing in 127 countries and territories. The AACR Annual Meeting program covers the latest discoveries across the spectrum of cancer research — from population science and prevention; to cancer biology, translational, and clinical studies; to survivorship and advocacy — and highlights the work of the best minds in research and medicine from institutions all over the world.

About FLAMINGO-01 and GLSI-100

FLAMINGO-01 (NCT05232916) is a Phase III clinical trial designed to evaluate the safety and efficacy of GLSI-100 (GP2 + GM-CSF) in HER2/neu positive breast cancer patients who had residual disease or high-risk pathologic complete response at surgery and who have completed both neoadjuvant and postoperative adjuvant trastuzumab based treatment. The

trial will be led by Baylor College of Medicine and will include US and international clinical sites from university-based hospitals and cooperative networks. In the double-blinded arms of the Phase III trial, approximately 500 HLA-A*02 patients will be randomized to GLSI-100 or placebo, and up to 100 patients of other HLA types will be treated with GLSI-100 in a third arm. The trial has been designed to detect a hazard ratio of 0.3 in invasive breast cancer-free survival, where 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. The trial is currently registered on clinicaltrials.gov and can be seen here. For future updates about FLAMINGO-01 please visit the Company's clinical trial tab at https://greenwichlifesciences.com/clinical-trials/.

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, a cell surface receptor protein that is expressed in a variety of common cancers, including expression in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or over-expressor) levels. In a completed randomized, single-blinded, placebo-controlled, multi-center Phase IIb clinical trial led by MD Anderson Cancer Center, no recurrences were observed in patients treated with GLSI-100 in the HER2/neu 3+ adjuvant setting after median 5 years of follow-up, if the patients were treated, followed, and remained disease free over the first 6 months, which is the time required to reach peak immunity and thus maximum efficacy and protection ($p = 0.0338$). For the 146 patients who have been treated with GLSI-100 to date over 4 clinical trials, treatment was well tolerated and no serious adverse events were observed related to the 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 Greenwich LifeSciences' most recent Annual Report on Form 10-K. 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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