November 10, 2021

Greenwich LifeSciences Provides Clinical Update on Upcoming Phase III Clinical Trial, FLAMINGO-01

- The GP2 Phase III clinical trial design was presented in a poster during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, providing an open label arm and potentially valuable data that can be analyzed and presented at any time starting in 2022. The interim analysis of the blinded, randomized pivotal arms will be reported midway through the trial approximately 3 years from the start of the trial.

- The GP2 Phase III clinical trial will be called FLAMINGO-01 and the combination of GP2 + GM-CSF will be called GLSI-100.

- At this time, at least 15 large university based hospitals and 4 clinical cooperative networks covering US and international sites are in discussions with the Company about participating in FLAMINGO-01 in addition to Baylor College of Medicine, the lead site. Study site recruitment will continue into 2022.

- The Company is currently completing the last steps to release GLSI-100 drug product vials to the clinical sites and to open clinical sites so patients can be screened, tested for HLA, and then enrolled and treated with GLSI-100 or placebo.

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 an update on the upcoming Phase III clinical trial FLAMINGO-01.

CEO Snehal Patel commented, “Our objective is to make GLSI-100 available to as many patients as possible as soon as possible. This will include opening FLAMINGO-01 in many clinical sites that are geographically situated to maximize access for patients. We continue to hear from patients interested in participating in our GLSI-100 trial and expect to be able to refer them to participating sites as appropriate. We recommend that patients or their physicians contact a participating clinical trial site near them once these sites have been opened and we communicate the participating sites to the public. We have been pleasantly surprised by the level of interest in our trial by major teaching hospitals led by breast cancer KOLs. While these sites may lead to strong enrollment, they may also lead to additional collaboration designed to optimize treatment with GLSI-100 in subsequent trials. We will be meeting with these KOLs at the upcoming in-person San Antonio Breast Cancer Symposium in December 2021 and look forward to opening the first sites and the trial soon thereafter.”

The trial is titled:

"A Randomized, Multicenter, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy and Safety of HER2/neu Peptide GLSI-100 (GP2 + GM-CSF) in HER2/neu Positive Subjects with Residual Disease or High-Risk PCR after both Neoadjuvant and Postoperative Adjuvant Trastuzumab-based Therapy (FLAMINGO-01)".

Vice President of Clinical and Regulatory Affairs, Dr. Jaye Thompson further commented, “The trial has been designed with an open label arm designed to provide a continual flow of data that can be publicly released, while preserving the blinding and randomization of the pivotal arms of the trial. Thus, we plan to continue to publish Phase IIb and Phase III trial data at conferences throughout the conduct of the Phase III study. The projected timeline to report the interim analysis data will depend on the rate of recurrences in both arms of the trial, but is estimated to be approximately 3 years from the time of first patient treatment. We are also making a major investment in commercial manufacturing now, which may allow for submission of a Biologics Licensing Application (BLA) to the FDA for conditional marketing approval of GLSI-100 based on the results of the interim analysis.”

Design features of the FLAMINGO-01 Phase III trial include:

- The Company has added more frequent sampling and testing of patients over longer time frames and plans to utilize improved technologies to analyze immune response.

- A third open-label arm treating up to 100 patients has been added to the Phase III trial to test GLSI-100 in HLA types other than HLA-A*02 and to assess immune response and clinical outcome. This third arm will function similar to a Phase II trial, thus creating potential for early immune response data analysis and proof of concept in other HLA types, which would expand GLSI-100’s market by HLA type from 50% up to 80% or more.

- The recurrence rate data from the third arm, along with injection site reaction and immune response data from any arm across all HLA types will be available for analysis throughout the study and may provide meaningful data until the interim analysis of the recurrence rate data from the blinded HLA-A*02 arms of the Phase III trial is completed.

- In both of the blinded, randomized, placebo-controlled HLA-A*02 arms of the Phase III trial, the approximately 500 patient trial design will include an event-driven interim analysis for superiority or futility. This analysis will be conducted when approximately half of the expected breast cancer recurrences or 14 events have occurred. While a hazard ratio of HR = 0 was observed in the Phase IIb trial, a more conservative HR = 0.3 was selected for the sizing of the Phase III trial with plans in place to adaptively adjust the size of the trial as necessary.

About FLAMINGO-01 and GLSI-100

The Phase III clinical trial will be called FLAMINGO-01 and the combination of GP2 + GM-CSF will be called GLSI-100. The Phase III trial is comprised of 2 blinded, randomized, placebo-controlled arms for approximately 500 HLA-A*02 patients and 1 open label arm of up to 100 patients for all other HLA types. An interim analysis has been designed to detect a hazard ratio of 0.3 in IDFS, 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 being registered on clinicaltrials.gov and the link and trial identifier will be published shortly. 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. 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 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

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Company Contact
Snehal Patel
Investor Relations
(832) 819-3232
info@greenwichlifesciences.com

Investor & Public Relations Contact for Greenwich LifeSciences
Dave Gentry
RedChip Companies Inc.
Office: 1-800-RED CHIP (733 2447)
Cell: (407) 491-4498
dave@redchip.com

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