May 23, 2022

Greenwich LifeSciences Provides Updates on Upcoming Phase III Clinical Trial & ASCO Meeting

- FDA review of manufacturing plans and pharmacy procedures associated with a recently placed clinical hold on the FLAMINGO-01 phase III clinical trial is underway with formal feedback from the FDA expected shortly. Greenwich is prepared to address FDA manufacturing and pharmacy procedure hold issues so that FLAMINGO-01 can commence as soon as possible.

- Negotiations of clinical trial contracts and budgets for the first 3 large hospital sites and the largest oncology network in the US are completed and in the execution phase, paving the way for site initiation visits and subsequent site activation. Following site activation, patients will be screened, tested for HLA type, randomized and enrolled into any of 3 arms, and treated. Patients who are interested in participating in the trial will be able to contact the Company by email at flamingo-01@greenwichlifesciences.com and will be able to keep up to date with the progress of the trial on clinicaltrials.gov with identifier NCT05232916 (view here).

- Company management will present 2 posters in person and will meet with clinical sites and networks participating in the upcoming FLAMINGO-01 phase III clinical trial at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting 2022, which will be held from June 3-7, 2022 in Chicago, Illinois.

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:

We have completed the manufacturing of GP2, released 3 clinical lots, and started the stability testing program for these lots. Previously, the FDA informally asked us to allow them to review an updated chemistry and manufacturing section on drug product before initiating the Phase III trial as our manufacturing information for the final drug product was incomplete and the lots were being tested for the first time. Subsequently, we received a formal clinical hold letter. Greenwich has provided a response and is working with the FDA to resolve all outstanding issues. All hold issues are associated with manufacturing and pharmacy procedures.

We continue to work toward study initiation. We are scheduling site initiation visits to train clinicians, nurses, coordinators, and pharmacists to activate and open clinical sites. We, along with our CRO, continue to actively recruit and prepare sites for site initiation.

Dr. Jaye Thompson, VP Clinical and Regulatory Affairs, commented, “We continue to make progress towards opening up our first sites. We just completed our first Data Safety Management Board (DSMB) meeting and are currently scheduling our initial Steering Committee Meeting with the lead clinicians of FLAMINGO-01. Our electronic data capture and inventory management systems are anticipated to go live in June. We are working to address all FDA issues rapidly so that the study can be initiated shortly.”

Three abstracts and two posters were accepted for presentation at the upcoming AACR Annual Meeting 2022. The titles of the abstracts are as follows:

- **Abstract Number**: LBA550; **Poster Number**: 322; **Abstract Title**: Evaluation of booster injections in maintaining peak immunity in a phase IIb study evaluating HER2/neu peptide GP2 (GLSI-100) versus GM-CSF alone after adjuvant trastuzumab in HER2 positive women with breast cancer.

- **Abstract Number**: e12519; **Abstract Title**: Baseline GP2 immune response as an independent prognostic factor in a phase IIb study evaluating HER2/neu peptide GP2 (GLSI-100) versus. GM-CSF alone after adjuvant trastuzumab in HER2-positive women with breast cancer.

- **Abstract Number**: TPS1110; **Poster Number**: 485b; **Abstract Title**: A randomized, multicenter, placebo-controlled, phase III study to evaluate the efficacy and safety of HER2/neu peptide GLSI-100 (GP2 + GM-CSF) in patients with residual disease or high-risk PCR after both neo-adjuvant and postoperative adjuvant anti-HER2 (Co-authored with Baylor College of Medicine)

CEO Snehal Patel commented, “These abstracts and posters highlight the first steps to optimizing the use of GLSI-100. We are planning to study the peak immunity of GP2 and how to assess when to administer booster injections. The current methodology is to deliver 6 primary injections over the first 6 months and 5 booster injections 6 months apart, thus totaling 11 injections over 3 years. However, in the future, we envision using immune response and T-cell profiles to determine when boosters may be needed. This may allow GLSI-100 to protect breast cancer survivors over longer periods of time against recurring metastatic breast cancer. In addition, approximately 20% of patients in the Phase IIb trial had a GP2 immune response before being treated with GP2, possibly due to a potential impending recurrence. We found that some patients with baseline immune response to GP2 tended to recur at faster rates. We are planning to study this observation in the Phase III trial, which could lead us to being able to use GP2 immune response as an independent prognosticator for impending recurrence. This would allow doctors to detect recurrences sooner than current standard of care and to thus start aggressive treatments sooner with potentially better outcomes.”

Mr. Patel further added, “This will be the first ASCO meeting in person since 2019, attended by oncologists from around the world. Greenwich is in discussions with 2 of the largest oncology networks in Europe for participation in FLAMINGO-01, and we look forward to expanding our outreach to potential international sites at ASCO. In the US, we anticipate that the largest oncology network will provide one of the first sites to treat patients and that a second oncology network in the US may participate along side. We believe that the participation of clinical trial networks focused on cancer treatment will help to increase the enrollment rate in FLAMINGO-01 and expand the geographic footprint to allow more patients

to participate.”

About the ASCO Annual Meeting

Founded in 1964, ASCO is the world's leading professional organization for physicians and oncology professionals caring for people with cancer. ASCO offers premier scientific events for oncology professionals, patient advocates, industry representatives, and major media outlets worldwide. The ASCO Annual Meeting program features poster presentations, poster discussion sessions, clinical science symposia, and dynamic education sessions about recent advancements in cancer research, treatment, and patient care. For more information, please visit the conference website at: https://conferences.asco.org/am/attend.

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 entitled "Risk Factors" in Greenwich LifeSciences' Annual Report on Form 10-K for the year ended December 31, 2021 and other periodic reports 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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