August 11, 2022

Greenwich LifeSciences Announces Activation of Clinical Sites and Commencement of Phase III Clinical Trial

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:

- Phase III clinical trial, Flamingo-01, has officially started
- Multiple sites have begun the screening and enrolling process
- Flamingo-01 is evaluating 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

CEO Snehal Patel commented, "We are thrilled to begin what we hope will be a successful reproduction of our Phase IIb trial, in which GLSI-100 safely prevented metastatic breast cancer recurrences with 100% disease free survival. The hard work and effort of the GLSI team and our partners have led us to this major milestone. We look forward to sharing more site contact information with patients and their clinicians in the future as we activate more sites and some of the largest oncology networks in the US and Europe, making Flamingo-01 available to as many patients as possible."

The commencement of the Phase III trial transitions the Company into pre-commercialization activities, which include:

- Working with the FDA in preparation for a BLA submission and commercial launch
- Implementing a global strategy for launching GP2 in international markets outside the US and Europe
- Initiating large scale manufacturing, packaging, and marketing

The Company anticipates the following additional activities/milestones:

- Phase III clinical trial progress and open label data will be presented at major conferences
- Licensing discussions may accelerate as the interim analysis approaches
- Other assets may be developed by acquisition or internal research, including T cell therapies that may be discovered in the Phase III trial by studying GP2's robust immunogenicity
- Additional patents for GP2 based on the Phase III trial findings, manufacturing, and pharmacy procedures are planned to be filed to extend patent life

For Patients Seeking to Participate in Flamingo-01

Patients who are interested in participating in the Flamingo-01 Phase III clinical trial can contact the Company by email at Flamingo-01@GreenwichLifeSciences.com and can obtain clinical site contact information to contact sites directly on www.clinicaltrials.gov with identifier NCT05232916 (view here).

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.

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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