February 1, 2022

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

- The GP2 Phase III clinical trial poster was presented in person at the 2021 annual San Antonio Breast Cancer Symposium (SABCS). The Company was a SABCS sponsor and held a clinical trial planning meeting with investigators at the conference. The poster can be seen here.

- Critical steps toward study initiation have been completed, including manufacturing, contracting with clinical trial partners, and setting up infrastructure.

- At least 25 sites are currently in the study start-up process at a variety of university-based hospitals and cooperative networks.

- Industry leaders for the Phase III clinical trial's Data Safety Monitoring Board have been recruited and the Steering Committee members are being confirmed.

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 Phase III clinical trial, FLAMINGO-01.

The Company has made significant progress towards study initiation:

- Contract Research Organization (CRO) has been contracted for study start-up, project management, data management, and clinical data monitoring

- Manufacturing of third clinical lot of GP2 using a commercial line has been completed

- Commercial lots of GP2 active ingredient for filing of BLA have been contracted

- Central Laboratory has been contracted for screening of HLA type

- Drug and biological sample storage sites and other study infrastructure have been put in place

- Central Institutional Review Board (IRB) approval has been granted for the study

- Clinical trial sites continue in the study start-up process and the Company continues to solicit additional US and international sites and networks for participation in the study

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. 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 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 any 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 the final prospectus related to the public offering filed with the SEC. 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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