March 3, 2022

# Greenwich LifeSciences Provides Updates on Upcoming Phase III Clinical Trial, Patent Filings, & AACR Meeting

- The Phase III clinical trial, Flamingo-01, is now registered on clinicaltrials.gov with identifier NCT05232916 (view here), where more details about the trial design and a preliminary listing of the initial clinical sites can be found
- Company management will be attending the upcoming American Association for Cancer Research (AACR) Annual Meeting 2022, which will be held from April 8-13, 2022 in New Orleans, Louisiana
- A GP2 Phase III clinical trial poster will be presented in-person to provide updates on the Phase III clinical trial, Flamingo-01, and to continue the recruitment of clinical sites
- Two additional posters will be presented in-person that cover additional findings from the Phase IIb clinical trial that we expect will lead to additional patent filings for the use of GLSI-100 in preventing recurring breast cancer
- With the completion of three clinical lots of GP2 for use in the Flamingo-01 trial, and in any additional clinical trials run in parallel, the Company intends to file additional patent claims surrounding the manufacturing of GP2 and the administration of GLSI-100

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:

The listing of the Flamingo-01 Phase III trial on clinicaltrials.gov provides clinicians and patients with an important source of information including trial updates and design, participating clinical sites, and contact information.

Three abstracts/posters were accepted for presentation at the upcoming AACR Annual Meeting 2022. The AACR plans to publish the 3 abstracts on April 8, 2022 and the 3 posters on April 11-12, 2022.

The Company anticipates making various patent filings that cover clinical use of GLSI-100, use of immune response data to improve patient treatment, manufacturing of GP2, and the administration and preparation of GLSI-100. If these patent claims are issued, they have the potential to extend the patent life of GP2 beyond 2040.

**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**

The Phase III clinical trial will be called FLAMINGO-01 and the combination of GP2 + GM-CSF will be called GLSI-100. In the double-blinded cohort of the Phase III trial, approximately 500 HLA-A*02 patients will be randomized to GLSI-100 or placebo and an open label cohort of up to 100 patients will be enrolled including all other HLA types. The trial has been designed to detect a hazard ratio of 0.3 in IBCFS, 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, NCT05232916, 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. 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 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 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 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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