

Greenwich LifeSciences Provides Financing Strategy & Corporate Update

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 believe that the Company is well capitalized with cash balance reported on the Company's Form 10-Q for the period ending March 31, 2022 of \$19.7 million
- Current burn rate has been low due to virtual corporate structure and outsourcing strategy
- Commencement of Phase III clinical trial, Flamingo-01, is expected to increase burn rate gradually over time as more sites are activated, patient treatment begins, and commercial manufacturing commences
- Recent "at the market" (ATM) sale agreement (see description below) entered into on July 12, 2022 with one of the leading biotech investment banks is a flexible financing vehicle designed to be used over time at share prices and quantities of shares at our sole discretion
- We intend to use the ATM facility opportunistically in the future and do not presently intend to use the full amount of the ATM facility
- We believe that strategic use of the ATM facility could begin our transition to an investment banking syndicate and to fundamental biotech institutional investors to complement the current retail investor base
- An update on the Flamingo-01 trial is expected to be provided shortly
- An update on the transition from the published Phase IIb data to future publications of open label Phase III data is expected to be provided shortly

About At the Market Sales Agreement

As disclosed in the Prospectus Supplement dated July 12, 2022, an ATM offering may be made from time to time through the investment bank by selling Company stock at the best available market price over time without a price discount and without warrants or additional dilutive financial structure. The number of shares that are sold will fluctuate based on the market price and demand for the Company's common stock, and any additional conditions set by the Company. It is not possible at this stage to predict the number of shares that will be sold or the gross proceeds to be raised in connection with those sales. There can be no assurance that the Company will sell any shares under or fully utilize this source of financing.

More specifically, each time the Company wishes to issue and sell shares of the Company's common stock under the sales agreement, the Company will notify the investment bank of the number of shares to be issued, the dates on which such sales are anticipated to be made, any limitation on the number of shares to be sold in any one day and any minimum price below which sales may not be made. The investment bank will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms on the open market or in block trades.

The Company currently intends to use the net proceeds from this offering for general corporate purposes, which may include, but are not limited to, funding the clinical development and manufacturing and other expenses for GP2, research and development, general and administrative expenses, license or technology acquisitions, and working capital and capital expenditures. The Company may also use a portion of the remaining net proceeds, if any, to acquire or invest in complementary businesses, products and technologies, although there are no current commitments or agreements with respect to any acquisitions as of the date hereof.

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 <u>https://greenwichlifesciences.com/clinical-trials/</u>.

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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