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Greenwich LifeSciences Announces Commencement of the First Commercial Line Filling of GP2

- The first commercial line filling of GP2 was commenced today, setting the scale and path forward for commercial manufacturing of GP2.

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 manufacturing and clinical updates on Phase III clinical trial FLAMINGO-01.

Over the past six months, the Company has been actively selecting and contracting partners to manufacture clinical and commercial lots of GP2 and to manage the Phase III clinical trial. An update on these activities follows:

- Today, the Company ran its first commercial fill line of GP2 at its fill and finish partner's production facility with sufficient scale to produce up to 80,000 doses of GP2 per lot. Three commercial lots of GP2 will be required to file a Biologics License Application (BLA) for GP2. The three lots combined should treat approximately 22,000 patients, and in the initial GP2 indication, approximately 17,000 new patients could be treated per year, saving up to 1,500 to 2,000 lives per year.
- Clinical research organization (CRO) has been engaged to manage the Phase III clinical trial.
- GP2 active ingredient manufacturer has been engaged to produce commercial scale GP2 lots.
- Commercial testing laboratory has been engaged to release clinical and commercial GP2 lots and to manage GP2 stability program.
- In addition to their operational role, these partners will play a key role in preparing the manufacturing and clinical information necessary to submit a BLA upon a successful interim analysis of the Phase III clinical trial.
- Partners for HLA typing, blood test collection, GP2 storage and distribution, GM-CSF distribution, immune response testing, and blood sample storage have been selected to support the Phase III clinical trial.

CEO Snehal Patel commented, "Commencing commercial scale manufacturing is a major milestone for the Company. We are carefully selecting partners who are leaders in the industry with whom we hope to work with over the long term. At the same time, the Company is developing a back-up strategy by location and function to reduce risk and provide multiple options going forward. In addition, all of the various parties required to operate the Phase III clinical trial testing, storage, and distribution activities have been

integrated well through our management team and CRO. The expertise of our partners has served to enhance the quality and accelerate the progress of our manufacturing and clinical plans."

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 and the link and trial identifier will be published shortly. 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 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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