November 18, 2020

Greenwich LifeSciences Announces Publication of Positive Phase IIb Clinical Trial Data for GP2, Its Lead Drug Candidate for the Prevention of Recurring Breast Cancer

– Company now preparing to enter a phase III clinical trial

– Phase IIb clinical trial was a prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites) trial led by MD Anderson and completed in 2018

– 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*)

– GP2 immunotherapy elicited a potent immune response measured by local skin tests and immunological assays

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 announced the publication of an abstract at the San Antonio Breast Cancer Symposium (SABCS). The abstract will be displayed as a poster on Wednesday, December 9, 2020 in a virtual format.

The study met all of its clinical endpoints for HER2/*neu* 3+ patients, concluding that the first 6 intradermal injections of GP2+GM-CSF safely elicited a potent immune response and reduced recurrence rates to 0% in HER2/*neu* 3+ patients, who received a standard course of trastuzumab after surgery, and this reduction of recurrence rate was maintained over the gold standard of 5 years of follow-up. A pivotal Phase III trial is being initiated to treat HER2/*neu* 3+ patients in the neoadjuvant setting. GP2 may also be effective when used in parallel to trastuzumab based therapeutics or in combination with trastuzumab based therapeutics in HER2/*neu* 1-2+ or other HER2/*neu* expressing cancers.

Snehal Patel, CEO of Greenwich LifeSciences, commented, "Approximately 50% of recurring patients do not respond to Herceptin or Kadcyla and still recur with metastatic breast cancer and a poor prognosis, where approximately 80-85% of recurring patients do not survive."

"The publication of this abstract shows that we met all of the endpoints for our Phase IIb

clinical trial for HER2/*neu* 3+ patients, including safety, where no serious adverse events were observed. By substantially reducing the recurrence rate of the non-responders, we are addressing a large unmet need of women. If we are successful in reproducing our Phase IIb clinical trial data in a Phase III clinical trial, we could make a major impact in reducing metastatic breast cancer recurrence in this patient population, potentially saving thousands of lives per year. We are excited to begin our Phase III clinical trial."

"Based on our analysis of the potential market in our IPO prospectus, GP2 could initially treat 17,000 newly diagnosed patients per year in the US or approximately 50% of the Herceptin adjuvant market of $2-3 billion, and could expand to 2.4x that of the Herceptin market through additional Phase II trials and indications, reaching a potential peak revenue exceeding $5 billion. Not included in these estimates are the 3 million breast cancer survivors in the US of whom 25% are HER2/*neu* 3+. These survivors could also be candidates for a safe and effective preventative therapy," Patel concluded.

The abstract highlights the final 5 year follow-up efficacy and demographic data across all patient populations from the completed prospective, randomized, placebo-controlled, single-blinded, multicenter, Phase IIb clinical trial evaluating the reduction of recurrences. The poster presentation includes the disease-free survival curves for both HER2/*neu* 3+ and HER2/*neu* 1-2+ patient populations, including the demographics for stage of cancer, hormone receptor status, node status, and prior treatment with chemotherapy, radiation, endocrine therapy, or trastuzumab.

This 168 patient (ITT: n=180) basket trial across 16 clinical sites explored 96 HER2/*neu* 3+ patients, who received a standard course of trastuzumab after surgery and subsequently completed the first 6 intradermal injections or placebo, starting GP2 treatment at median 17.1 months after surgery, and 72 HER2/*neu* 1-2+ patients, who did not receive trastuzumab after surgery and subsequently completed the first 6 intradermal injections or placebo, starting the GP2 treatment at median 10.8 months after surgery.

Since GP2 is synergistic with trastuzumab, and the HER2/*neu* 1-2+ patients did not receive trastuzumab, it was prespecified to compare recurrence rates ITT versus per protocol in these 2 distinct, independently reported populations, excluding those patients who did not complete the first 6 intradermal injections. GP2 was shown to be well tolerated with no SAEs and elicited a potent immune response measured by local skin tests and immunological assays, which suggest peak immunity is reached at 6 months upon completion of the first 6 intradermal injections.

After 5 years of follow-up, the Kaplan-Meier estimated 5-year DFS rate in the 46 HER2/*neu* 3+ patients treated with GP2+GM-CSF, if the patient completed the first 6 intradermal injections, was 100% versus 89.4% (95% CI:76.2, 95.5%) in the 50 placebo patients treated with GM-CSF ($p = 0.0338$). The treated versus placebo HER2/*neu* 3+ patients were well-matched, where approximately 53% were stage T1, 41% were stages T2-T4, 55% were node positive, 58% were HR positive and received endocrine therapy, 77% received adjuvant radiation, 77% received adjuvant chemotherapy, and 89% received trastuzumab. There was no benefit to GP2 treatment in the HER2/*neu* 1-2+ patients where trastuzumab was not administered.

Abstract PS10-23 is entitled: Five year median follow-up data from a prospective, randomized, placebo-controlled, single-blinded, multicenter, Phase IIb study evaluating the

reduction of recurrences using HER2/*neu* peptide GP2 + GM-CSF vs. GM-CSF alone after adjuvant trastuzumab in HER2/*neu* positive women with operable breast cancer. The full abstract can be viewed here on page 654.

About SABCS

The 43rd annual SABCS has grown to be the industry's premier breast cancer conference for basic, translational, and clinical cancer research professionals. It is well-known for presenting the latest breast cancer data from all over the world. More than 7,500 health care professionals from more than 90 countries attend annually. Baylor College of Medicine became a joint sponsor of SABCS in 2005. The Cancer Therapy & Research Center at UT Health Science Center San Antonio and American Association for Cancer Research began collaborations with SABCS in 2007. For more information, please visit the conference website at: https://www.sabcs.org/

About Breast Cancer and HER2/*neu* Positivity

One in eight U.S. women will develop invasive breast cancer over her lifetime, with approximately 266,000 new breast cancer patients and 3.1 million breast cancer survivors in 2018. 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 GP2 to date over 4 clinical trials, GP2 treatment was well tolerated and no serious adverse events were observed related to GP2 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: www.greenwichlifesciences.com

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. 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 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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Company Contact
Snehal Patel
Investor Relations
(832) 819-3232
info@greenwichlifesciences.com

Investor & Public Relations Contact for Greenwich LifeSciences Inc.:
Dave Gentry
RedChip Companies Inc.
Office: 1-800-RED CHIP (733 2447)
Cell: (407) 491-4498
dave@redchip.com

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