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Greenwich LifeSciences Announces Second Publication and Second Poster Presentation of Phase III Clinical Trial of Potential Breakthrough Technology for Recurring Breast Cancer

– Phase III clinical trial to be led by Baylor College of Medicine

– In the Phase IIb clinical trial, led by MD Anderson, 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), with robust immune response, well-tolerated safety profile, and no reported serious adverse events

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 a second abstract at the San Antonio Breast Cancer Symposium (SABCS), jointly authored by Professor Mothaffar F. Rimawi, the Global Principal Investigator of the GP2 Phase III clinical trial, and the Executive Medical Director and Co-Leader of the Breast Cancer Program at the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine, and Professor C. Kent Osborne, Tina and Dudley Sharp Chair in Oncology and the founding Director of the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine. The abstract will be displayed as the Company's second poster on Wednesday, December 9, 2020 in a virtual format with an introductory audio track.

The abstract highlights the design of the planned Phase III clinical trial. The trial is designed as a single registration trial that will include an interim analysis seeking conditional marketing approval from the FDA upon the interim analysis data read out followed by submission of a Biologics Licensing Application. The Phase III clinical trial aims to reproduce the Phase IIb study which concluded that completion of 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.

Snehal Patel, CEO of Greenwich LifeSciences, commented, "The participation of Baylor College of Medicine as the Phase III clinical trial lead site further validates the significance of our Phase IIb data. Reducing the recurrence of breast cancer rates to 0% gives us great confidence as we try to reproduce this data in the Phase III clinical trial. We are addressing a potential market of up to $5 billion in a disease that affects 1 in 8 women, who if recur, will likely face metastatic breast cancer."

“We are very excited to be working with such prominent key opinion leaders. Professor Rimawi’s leadership of our Phase III clinical trial will complement the positive Phase IIb clinical trial results with the research and clinical expertise of Baylor College of Medicine. Due to GP2’s efficacy and safety profile, GP2 immunotherapy may provide clinicians with an option to reduce the use of other toxic and expensive treatments. We look forward to sharing our Phase IIb clinical trial data and Phase III clinical trial design with breast cancer leaders attending SABCS and to discussing the participation of their clinical sites in our trial,” Patel concluded.

The Phase III clinical trial will explore the use of GP2 + GM-CSF as adjuvant therapy to prevent the recurrence of breast cancer in HER2/*neu* positive and HLA 2+ patients, post-surgery and following the first year of treatment with any trastuzumab-based therapy.

The Phase III clinical trial is a prospective, randomized, double-blinded, multi-center study. After 1 year of trastuzumab-based therapy or an approved biosimilar, treatment with GP2 + GM-CSF or placebo will be administered intradermally for the 6 primary immunization series over the first 6 months and 5 subsequent boosters over the next 2.5 years for a total of 11 injections over 3 years of treatment. The participant duration of the trial will be 3 years of treatment plus 2 years of follow-up for a total of 5 years following the first year of treatment with trastuzumab-based therapy or approved biosimilar. An interim analysis is planned and patients will be stratified based on prior and current treatments, among other factors.

The majority of breast cancer patients will be HER2/*neu* positive and HLA 2+, disease-free, conventionally treated node-positive, post breast tumor removal surgery and following the first year of treatment with trastuzumab-based therapy.

Abstract OT-13-03 is entitled: A prospective, randomized, multicenter, double-blinded, placebo-controlled Phase III trial of the HER2/*neu* peptide GP2 + GM-CSF versus bacteriostatic saline/WFI placebo as adjuvant therapy after any trastuzumab-based therapy in HER2-positive women with operable breast cancer. The full abstract can be viewed here on page 912.

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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