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## Greenwich LifeSciences, Inc. Announces Acceptance of Two Abstracts at Upcoming Major Breast Cancer Conference

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 that two abstracts have been accepted for presentation at the upcoming San Antonio Breast Cancer Symposium (SABCS), including two corresponding posters. SABCS 2020 will be held in a virtual format from December 8-11, 2020. SABCS anticipates publishing the abstracts in late November 2020 and the posters on December 9, 2020.

Snehal Patel, CEO of Greenwich LifeSciences, commented, "While we previously reported that in the GP2 Phase IIb clinical trial that no recurrences were observed in the HER2/*neu* 3+ adjuvant setting after 5 years of follow-up if the patient received their primary GP2 treatments, we are pleased to be able to present the final 5 year analysis, including Kaplan-Meier disease free survival curves and patient demographics."

Dr. F. Joseph Daugherty, CMO of Greenwich LifeSciences, commented, "We look forward to sharing this data with breast cancer key opinion leaders as we recruit clinicians and clinical sites for participation in our planned Phase III clinical trial. This data will further advance the development of GP2 and support our common goal to provide patients and clinicians with a safe and effective treatment option to prevent recurrences following surgery, and thereby prevent metastatic breast cancer."

The first abstract and poster will present 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 study evaluating the reduction of recurrences. The presentation will include 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.

The second abstract and poster will present the design of the planned Phase III clinical trial. The trial is designed as a single registration trial which 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 (BLA).

The 2 abstracts and posters are entitled:

**Program Number: PS10-23** - 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 positive women with operable breast cancer

**Program Number: OT-13-03** - 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

## **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](http://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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