

# Greenwich LifeSciences Reports Robust Immune Response Phase IIb Data Supporting GP2 Clinical Outcome of 0% Metastatic Breast Cancer Recurrences Over 5 Years of Follow-up

- Abstract published today at the American Association for Cancer Research (AACR)
   Annual Meeting shows the GP2 final 5 year immune response data from the Phase IIb clinical trial.
- Poster showing graphs of immune response data over time will be published by AACR on Saturday, April 10th at 8:30 am ET. The Company plans to publish the poster, the abstract, and an audio recording in a joint press release on April 10th.
- Potent immune response data supports the previously reported clinical outcome of 0% metastatic breast cancer recurrences over 5 years of follow-up.
- Statistically significant peak immunity was reached after 6 months of GP2 treatment as measured in both a GP2 specific CD8 T cell dimer binding assay and a delayed-typehypersensitivity (DTH) skin test.
- HER2 3+ population immune response was similar to the HER2 1-2+ population immune response, suggesting the potential to treat the HER2 1-2+ population (including triple negative breast cancer) with GP2 immunotherapy in combination with trastuzumab (Herceptin) based products and other clinically active agents.
- Broad based immune response suggests that GP2 immunotherapy and Herceptin based products may also have the potential to treat other HER2 1-3+ expressing cancers.

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 abstract results of the final 5 year immune response data of the Phase IIb clinical trial at the 2021 AACR Annual Meeting. Immune response is the primary mechanism of action and is critical to developing dosing and booster treatment strategies that are designed to achieve and sustain peak immunity and to prevent metastatic breast cancer recurrences.

The AACR published the Phase IIb final 5 year immune response data abstract on Friday, April 9th and plans to publish the corresponding poster on Saturday, April 10th. The poster, the abstract, and an audio recording will be published by the Company on Saturday, April 10th in a joint press release.

**Summary of Additional Upcoming Posters/Press Releases:** 

Week of April 12th – Press release of the second poster at AACR, co-sponsored by the Company and the Baylor College of Medicine, will provide more details behind the updated design of the planned Phase III clinical trial.

Week of June 4th – The Company will present two abstract/poster presentations at the 2021 American Society of Clinical Oncology (ASCO) conference. The poster presentations will include the final 5 year safety data of the GP2 Phase IIb clinical trial and an introduction to the interim analysis and clinical strategy of the planned Phase III clinical trial.

#### 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 at <a href="https://www.greenwichlifesciences.com">www.greenwichlifesciences.com</a> and follow the Company's Twitter at <a href="https://twitter.com/Greenwichls">https://twitter.com/Greenwichls</a>.

#### **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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