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Greenwich LifeSciences Updates 2021 Timeline & Announces Two Upcoming Presentations at the American Association for Cancer Research Annual Meeting

- Presenting final 5 year immune response data from the Phase IIb clinical trial for recurring breast cancer
- Planning completion of GP2 manufacturing in 2nd/3rd quarter of 2021
- Presenting updated design for Phase III clinical trial that is planned to commence in 3rd/4th quarter of 2021

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 titles and authors of the two abstracts/posters that were accepted for presentation at the upcoming American Association for Cancer Research (AACR) Annual Meeting 2021, which will be held in a virtual format from April 10-15, 2021.

The AACR plans to publish the abstracts on April 9, 2021 at 12:01 am EST and the posters on April 10, 2021.

Snehal Patel, CEO of Greenwich LifeSciences, commented, "The first AACR abstract and poster will focus on the final 5 year analysis of the immune response over time for all patients in our Phase IIb clinical trial. The immune response data will be critical to finalizing the Phase III clinical trial design, including the interim analysis and immune response monitoring strategy. For example, one could conceivably monitor the quality of dosing at each clinical site by monitoring immune response by clinical site, as well as assess immune response by multiple HLA types, separating responders from non-responders."

Mr. Patel further added, "Sufficient manufacturing progress has been made in the 1st quarter of 2021, such that the completion of GP2 manufacturing is planned for 2nd/3rd quarter of 2021. Thus, with the updated AACR data and finalization of the clinical trial protocol and with the shipment of GP2 drug product to clinical sites, enrollment of the first patients in the Phase III clinical trial could commence in the 3rd/4th quarter of 2021."

Mr. Patel concluded, "In addition to our strategy for HER2/*neu* 3+ patients stated above, analysis of the immune response data in the HER2/*neu* low to intermediate expressing (HER2/*neu* 1-2+) patient populations in our Phase IIb clinical trial may be helpful in designing strategies to treat these patients, which include triple negative breast cancer patients, an area of substantial unmet need. It may be possible to design trials that combine

GP2 and Herceptin antibody drug conjugates (ADCs) with other clinically active HER2/*neu* peptides and immune stimulating therapies, such as checkpoint inhibitors. This multi-technology strategy could also be used to treat the many other types of HER2/*neu* expressing cancers."

Final 5 Year Recurrence Rate / Disease Free Survival Data: In December 2020, the Company presented the Phase IIb clinical trial efficacy data, including clinical outcome and recurrence rate data. The Kaplan Meier analysis of disease free survival for HER2/*neu* 3+ patients treated with GP2 immunotherapy showed 100% disease survival over 5 years of follow-up (0% breast cancer recurrences, $p = 0.0338$) if the patients received their primary GP2 treatments following surgery and Herceptin treatment.

Final 5 Year Immune Response Data: At the upcoming AACR 2021 conference, in the first abstract and poster, the Company will present the Phase IIb clinical trial final 5 year immune response data over time across all patient populations to complement the December 2020 efficacy data. The immune response is the primary mechanism of action that is critical to developing dosing and booster treatment strategies designed to achieve and sustain peak immunity. The presentation will include analysis of delayed type hypersensitivity skin tests and immunological assays used to measure immune responses for both HER2/*neu* 3+ and HER2/*neu* 1-2+ patient populations, such as a comparison of peak immune response versus baseline immune response at multiple time points.

Final 5 Year Safety Data: At a future conference in 2021, the Company plans to present the Phase IIb clinical trial final 5 year safety data. To date, the Company has administered GP2 immunotherapy to 138 patients in four clinical trials, where no serious adverse events and a well tolerated safety profile have been reported.

Updated Phase III Clinical Trial Design: At the upcoming AACR 2021 conference, in the second abstract and poster, the Company and the Baylor College of Medicine will present the updated design of the planned Phase III clinical trial. The clinical 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 the submission of a Biologics Licensing Application (BLA). Additional features of the clinical trial design will be presented to breast cancer key opinion leaders as the Company and the Principal Investigators recruit clinicians and clinical sites for participation in the Phase III clinical trial.

The numbers, titles, and authors of the Company's abstracts and E-posters are as follows:

Abstract/Poster Number & Title: CT183 - Final five year median follow-up data from a prospective, randomized, placebo-controlled, single-blinded, multicenter, phase IIb study evaluating a time series of immune responses using HER2/*neu* peptide GP2 + GM-CSF vs. GM-CSF alone after adjuvant trastuzumab in HER2 positive women with operable breast cancer

Authors can be viewed here:
https://www.abstractsonline.com/pp8/#!/9325/presentation/5254

Abstract/Poster Number & Title: CT256 - 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

Authors can be viewed here:
https://www.abstractsonline.com/pp8/#!/9325/presentation/4862

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 www.greenwichlifesciences.com and follow the Company's Twitter at https://twitter.com/GreenwichLS.

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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