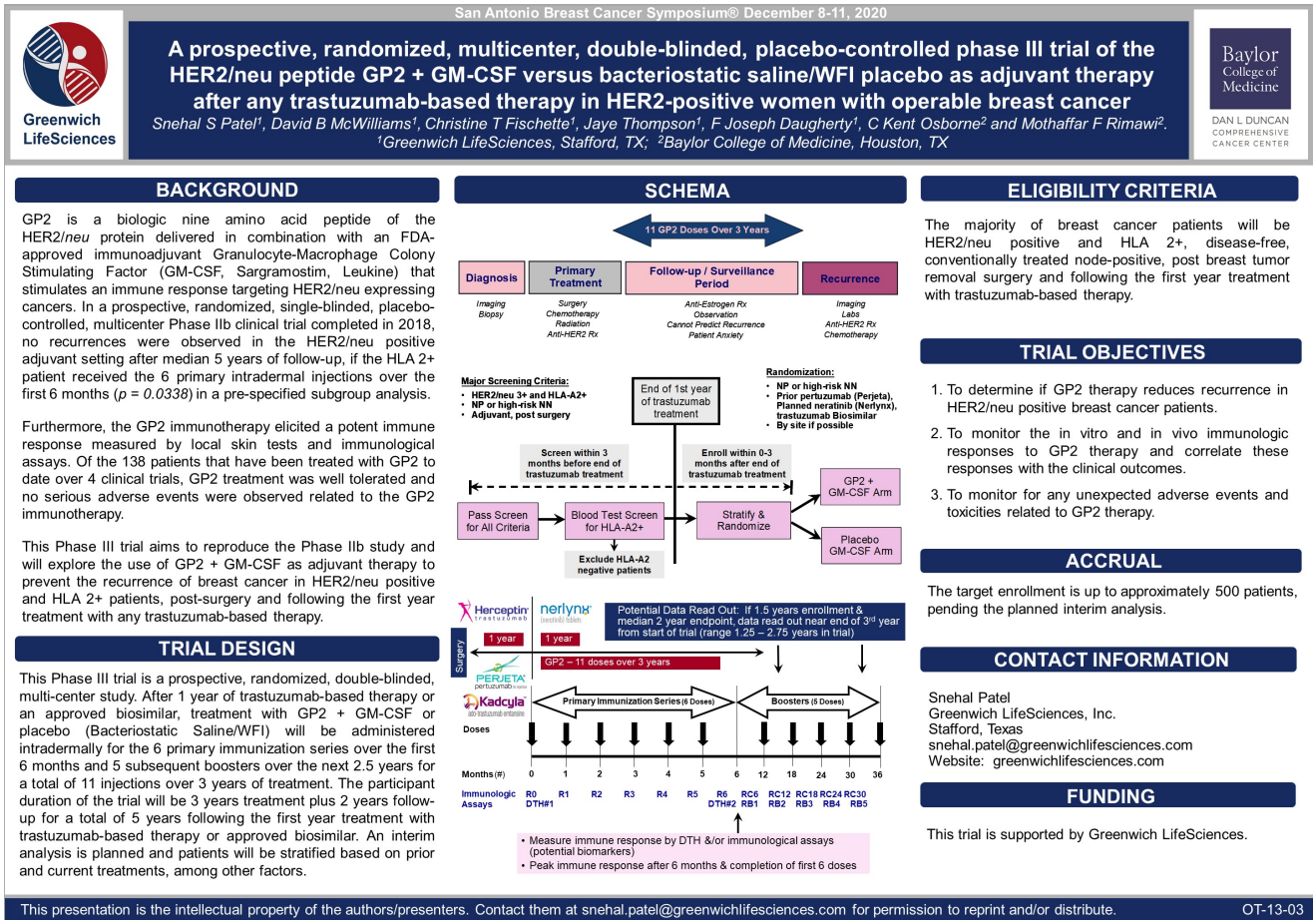
December 11, 2020

Greenwich LifeSciences Announces Poster Presentation on Its GP2 Phase III Clinical Trial Design for Recurring Breast Cancer

– The GP2 Phase III clinical trial design was presented during the 2020 San Antonio Breast Cancer Symposium (SABCS) and introduced by the Global Principal Investigator, Professor Mothaffar F. Rimawi of Baylor College of Medicine

– In the Phase IIb clinical trial, led by MD Anderson, a 0% recurrence rate was observed in the HER2/*neu* 3+ adjuvant setting after median 5 years of follow-up if the patient received the 6 primary intradermal injections of GP2 immunotherapy over the first 6 months ($p = 0.0338$), and a robust immune response, a well-tolerated safety profile, and no serious adverse events were reported



Poster OT-13-03: GP2 Phase III Clinical Trial Design for Recurring Breast Cancer (Graphic: Business Wire)

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 poster for the GP2 Phase III clinical trial design for recurring breast cancer at the San Antonio Breast Cancer Symposium (SABCS) in a virtual format. The Global Principal Investigator of the GP2 Phase III clinical trial, Dr. Mothaffar F. Rimawi of the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine, is the lead author of the poster and has recorded an audio track providing an overview. The full poster with audio can be accessed or downloaded here on the Company website, as well as on the conference website by attendees.

Poster 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 Phase III 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 readout, after which a Biologics Licensing Application will be submitted. The Phase III clinical trial aims to reproduce the Phase IIb clinical trial that concluded that the 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, "We are preparing diligently for our pivotal Phase III clinical trial, aligning ourselves with one of the leading cancer institutions in the world. We appreciate the overwhelming response to our first poster, where we reported the final efficacy results of our Phase IIb clinical trial showing no breast cancer recurrences in HER2/*neu* 3+ patients if they were fully immunized with GP2. Our partnership with Dr. Rimawi and Baylor College of Medicine gives us great confidence in our objective to replicate this data in the Phase III clinical trial."

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. The majority of the patient population will be HER2/*neu* positive, HLA 2+, disease-free, conventionally treated node-positive, post- surgery, and post- first year of treatment with trastuzumab. An interim analysis is planned and patients will be stratified based on prior and current treatments, among other factors.

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/

Baylor College of Medicine

Baylor College of Medicine (www.bcm.edu) in Houston is recognized as a health sciences university and is known for excellence in education, research and patient care. It is the only private medical school in the greater southwest and is ranked 22nd among medical schools for research and 4th for primary care by *U.S. News & World Report*. Baylor is listed 21st among all U.S. medical schools for National Institutes of Health funding and No. 1 in Texas. The Baylor pediatrics program is ranked 6th among all pediatric programs, reflecting the strong affiliation with Texas Children's Hospital where our faculty care for pediatric patients and our students and residents train. Nationally, our physician assistant program was ranked 3rd in the health disciplines category and our nurse anesthesia program ranked 2nd. Located in the Texas Medical Center, Baylor has affiliations with seven teaching hospitals and jointly owns and operates Baylor St. Luke's Medical Center, part of CHI St. Luke's Health. Currently, Baylor has more than 3,000 trainees in medical, graduate, nurse anesthesia, physician assistant, orthotics and genetic counseling as well as residents and postdoctoral fellows. Follow Baylor College of Medicine on Facebook (http://www.facebook.com/BaylorCollegeOfMedicine) and Twitter (http://twitter.com/BCMHouston).

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
Dave Gentry
RedChip Companies Inc.
Office: 1-800-RED CHIP (733 2447)
Cell: (407) 491-4498
dave@redchip.com

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