

March 8, 2021



# Greenwich LifeSciences Hires Industry Expert, Dr. Jaye Thompson, to Manage Phase III Clinical Trial for Recurring Breast Cancer

- Actively involved in over 200 clinical trials
- 30 years experience in managing clinical trials and FDA interactions, leveraging biostatistics PhD
- Founding partner of multiple CROs

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 hiring of Jaye Thompson, PhD as Vice President Clinical and Regulatory Affairs to oversee the upcoming GP2 Phase III clinical trial on a full time basis.

Dr. Thompson commented, "I am excited to begin managing our Phase III clinical trial for recurring breast cancer. Our drug is addressing a critical unmet need. Over 3 million U.S. breast cancer survivors need safe and effective drugs to prevent metastatic breast cancer recurrence. The fact that our GP2 Phase IIb clinical data showed no breast cancer recurrences over 5 years gives me confidence that GP2 has the potential to save hundreds of thousands of lives and to return affected women back to normal and healthy lives. I look forward to leveraging my prior experiences in protocol and trial design, clinical trial start-up activities, clinical trial management, statistical analysis of clinical and biomarker data, and management of relationships with U.S. and European regulators as we commence the GP2 Phase III trial. I am also committed to exploring all viable regulatory pathways to make GP2 available to clinicians and patients as soon as possible."

Snehal Patel, CEO of Greenwich LifeSciences, commented, "We are very fortunate that Dr. Thompson is joining the Company on a full time basis. While she has been invaluable in advising the Company in the past, her expanded role and responsibilities will allow the Company to start enrolling patients in the planned Phase III clinical at multiple sites, giving us an even stronger start as we seek to reproduce our promising Phase IIb clinical trial results. Dr. Thompson will be responsible for overseeing the GP2 Phase III clinical trial as we finalize the protocol, engage outside CRO support, recruit sites, and coordinate with the Baylor College of Medicine, our lead site. Under her leadership, we have already engaged a CRO and statistician to assist us in start-up activities. In addition, her vast experience will help us to optimize the utilization of our cash resources as we allocate them towards completing the interim analysis and data read out of the Phase III trial and towards a

potential filing of a BLA for conditional marketing approval of GP2.”

Dr. Thompson has over 30 years of experience in pharmaceutical and device product development. She was a co-founder and Chief Operating Officer of Proxima Clinical Research, a founder and former President of Synergos, and leader at inVentiv Clinical Solutions, which are clinical research service providers. In these positions, Dr. Thompson supported clinical stage companies in strategic clinical and regulatory planning, as well as in the execution of those plans. Dr. Thompson previously led the clinical and regulatory affairs efforts at Repros Therapeutics and Opexa Therapeutics. She has directed and managed statistical analysis, data management, report writing, and the conduct of clinical trials for a wide variety of indications. Dr. Thompson has been actively involved in over 200 clinical trials for drugs, biologics, and devices, and she has been associated with numerous FDA regulatory submissions and has represented sponsor companies at FDA meetings and advisory committee meetings. Dr. Thompson was appointed to the Governor’s Texas Emerging Technology Fund Advisory Committee. She received a BS in Applied Mathematics from Texas A&M University and an MS and a PhD in Biostatistics from the University of Texas Health Science Center in Houston.

### **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](http://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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20210308005345/en/>

### **Company Contact**

Snehal Patel

Investor Relations

(832) 819-3232

[info@greenwichlifesciences.com](mailto: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](mailto:dave@redchip.com)

Source: Greenwich LifeSciences, Inc.