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Greenwich LifeSciences Expands Role of Industry Expert Dr. F. Joseph Daugherty to Include Medical Monitor for its Upcoming Phase III Clinical Trial

- Dr. Daugherty has 40+ years of experience managing biotechnology projects and companies focused on cancer, immunology, vaccines, and nutraceuticals
- Dr. Daugherty will serve as medical monitor for the upcoming Phase III clinical trial and for potential future clinical trials, focusing on assessing any safety issues that arise on a real-time basis, leveraging his MD from the University of Nebraska Medical Center and prior experience as a medical monitor for oncology-related clinical trials.

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 expansion of Dr. F. Joseph Daugherty's role to include the critical responsibility of Medical Monitor of the Phase III clinical trial and a long-term agreement to serve as Chief Medical Officer.

Dr. Daugherty commented, "I look forward to supporting the GLSI-100 clinical trials as Medical Monitor. While GP2 has been shown to be both effective and safe in the Phase IIb trial, we will maintain our vigilance in the larger Phase III trial. The mild local and systemic reactions observed in the Phase IIb trial have served to further validate the immune response and mechanism of action of GP2, thus requiring the balancing of dosing to ensure that local and systemic reactions are tolerable and safe, yet still sufficiently robust enough to lead to the prevention of metastatic breast cancer recurrence."

CEO Snehal Patel added, "We are very excited that Dr. Daugherty is expanding his role with a very significant commitment to serve as medical monitor of our upcoming and future clinical trials as we seek to expand GP2's potential to all HER2 positive breast cancer patients and to explore HER2 low breast cancer and other HER2 expressing cancers. While we have not seen any serious adverse events in the 138 patients we have treated to date across four clinical trials attributable to GP2 immunotherapy, Dr. Daugherty's responsibility to oversee the safety of our Phase III trial will be a key component of our regulatory strategy in this potential single registration trial."

Dr. Daugherty has over 40 years of experience in managing and overseeing biotechnology and biomedical projects. He served first as President and recently as Chief Executive Officer, Chief Medical Officer, and the Chairman of the board of directors of Eleos, Inc., a

clinical-stage, private biotech company focused on anti-sense technology in hematologic cancers. In addition to being an officer and director, Dr. Daugherty has served in various other capacities, including as a management consultant to over 20 public and private biomedical companies including Dupont, Inc, and as President of ConAgra's biotech division. He received a BA in Biology from Washington University, a MD from the University of Nebraska, and a MS in Industrial Administration from Carnegie Mellon University.

About FLAMINGO-01 and GLSI-100

The Phase III clinical trial will be called FLAMINGO-01 and the combination of GP2 + GM-CSF will be called GLSI-100. The Phase III trial is comprised of 2 blinded, randomized, placebo-controlled arms for approximately 500 HLA-A*02 patients and 1 open label arm of up to 100 patients for all other HLA types. An interim analysis has been designed to detect a hazard ratio of 0.3 in IDFS, where 28 events will be required. An interim analysis for superiority and futility will be conducted when at least half of those events, 14, have occurred. This sample size provides 80% power if the annual rate of events in placebo-treated subjects is 2.4% or greater. The trial is currently being registered on clinicaltrials.gov and the link and trial identifier will be published shortly. For future updates about FLAMINGO-01 please visit the Company's clinical trial tab at https://greenwichlifesciences.com/clinical-trials/.

About Breast Cancer and HER2/*neu* Positivity

One in eight U.S. women will develop invasive breast cancer over her lifetime, with approximately 282,000 new breast cancer patients and 3.8 million breast cancer survivors in 2021. 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 GLSI-100 to date over 4 clinical trials, treatment was well tolerated and no serious adverse events were observed related to the 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.

About GP2 Immunotherapy Immune Response

As previously reported, GP2 immunotherapy generated GP2-specific immune responses, leading to no metastatic breast cancer recurrence in the HER2/*neu* 3+ population in the

Phase IIb clinical trial, thus supporting GP2's mechanism of action. Statistically significant peak immunity was reached after 6 months of GP2 treatment, as measured in both the Dimer Binding Assay and the DTH skin test. HER2/*neu* 3+ population immune response was similar to the HER2/*neu* 1-2+ population immune response, suggesting the potential to treat the HER2/*neu* 1-2+ population (including triple negative breast cancer) with GP2 immunotherapy in combination with trastuzumab (Herceptin) based products and other clinically active agents. The broad based immune response suggests the potential for GP2 to treat other HER2/*neu* 1-3+ expressing cancers. For more information on GP2 immune response and clinical data, please visit the Company's clinical trial tab at https://greenwichlifesciences.com/clinical-trials/.

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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