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Greenwich LifeSciences, Inc. Announces Completion of Manufacturing of Drug for its Planned Phase III Clinical Trial

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 completion of the manufacturing of the GP2 active ingredient for its planned Phase III clinical trial. After having met all drug specifications and release criteria in compliance with current Good Manufacturing Practice (cGMP), the GP2 active ingredient has been released for formulation and filling into vials, which is the last step before storage and distribution of GP2 to clinical sites.

Snehal Patel, CEO of Greenwich LifeSciences commented, "We are pleased to have completed this major manufacturing milestone. Last week we completed our IPO, in which members of senior management and directors invested funds aggregating in approximately 15% of the IPO gross proceeds. Our success in scaling up GP2 to large scale cGMP manufacturing and our recent fundraising moves us closer to commencing the upcoming Phase III clinical trial."

The Company's commercial manufacturing partner, Polypeptide Laboratories, located in San Diego, California and a specialist in the manufacture of clinical and commercial grade peptides, initiated this clinical lot in 2019, which is at a commercial scale that can produce 50,000 doses and treat up to 4,500 patients. In addition, analytical methods were validated and a stability program has been initiated per cGMP requirements.

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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