January 22, 2025

Greenwich LifeSciences Provides Update on Commercial Manufacturing

STAFFORD, Texas, Jan. 22, 2025 (GLOBE NEWSWIRE) -- Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the "Company"), a clinical-stage biopharmaceutical company focused on its Phase III clinical trial, FLAMINGO-01, which is evaluating GLSI-100, an immunotherapy to prevent breast cancer recurrences, today provided the following update on the commercial manufacturing of GP2.

Preparation for Filing of BLA in the US

In addition to the submission of the Phase III clinical data, submitting commercial manufacturing data will be critical to the filing of a Biological License Application (BLA) for GLSI-100 in the US and for regulatory filings in other countries.

Commercial Manufacturing

The first three commercial lots of GP2 active ingredient were manufactured in 2023 in an approved commercial facility, which could be used to prepare approximately 200,000 doses of GP2. In addition, drug stability programs have been initiated. Data on these commercial lots were submitted to the FDA in the US and European regulators (EMA) in Europe and will continue to be reviewed.

In 2024, the first of three commercial lots filling GP2 into vials for commercial sale or for clinical use was manufactured in an approved commercial facility, and final testing of this first lot is nearing completion. The Company may choose to use these finished commercial vials in FLAMINGO-01, subject to regulatory review.

CEO Snehal Patel commented, "We are pleased to have made substantial progress in the commercial manufacturing of GP2 in 2023 and 2024. We have now manufactured GP2 vials that can be stored in preparation for commercial launch or used in clinical trials. We will be manufacturing at least two more lots of finished GP2 product. Our plan is to complete these activities in parallel to conducting FLAMINGO-01 so that both clinical and manufacturing data are available for review by the biologics division of the FDA prior to potentially being granted a marketing license with up to 12 years of market exclusivity based on current law."

Mr. Patel further added, "Establishing a trade name for GP2 and a strategy for packaging of GP2 or GLSI-100 for commercial sale by country will be an upcoming priority as we near the filing of a BLA in the US. Furthermore, with the expansion of clinical sites into Europe and the on-going regulatory review of the manufacturing of GP2 by EMA, an additional priority will be to discuss the marketing license pathway in Europe with EMA. The objective is to manufacture GP2 and to conduct FLAMINGO-01 in a manner that is acceptable to both US and European regulators, even where regulatory standards may differ. Our manufacturing

partners, who can ramp up manufacturing scale as needed, and the up to 150 participating clinical sites in the US and Europe at some of the most prominent institutions and teaching hospitals, who are becoming familiar with the use of GLSI-100 in the clinic, may provide for an efficient transition to product launch and commercial sales if GLSI-100 is approved."

New Intellectual Property

In 2024, additional refinements were made towards finalizing the manufacturing of GP2, the reconstitution of GLSI-100 in the pharmacy, and the injection of GLSI-100 in the clinic. As a result, the Company may potentially file additional patent applications.

About FLAMINGO-01 and GLSI-100

FLAMINGO-01 (NCT05232916) is a Phase III clinical trial designed to evaluate the safety and efficacy of GLSI-100 (GP2 + GM-CSF) in HER2 positive breast cancer patients who had residual disease or high-risk pathologic complete response at surgery and who have completed both neoadjuvant and postoperative adjuvant trastuzumab based treatment. The trial is led by Baylor College of Medicine and currently includes US clinical sites from university-based hospitals and cooperative networks with plans to expand into Europe and to open up to 150 sites globally. In the double-blinded arms of the Phase III trial, approximately 500 HLA-A*02 patients will be randomized to GLSI-100 or placebo, and up to 250 patients of other HLA types will be treated with GLSI-100 in a third arm. The trial has been designed to detect a hazard ratio of 0.3 in invasive breast cancer-free survival, 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.

For more information on FLAMINGO-01, please visit the Company's websitehere and clinicaltrials.gov here. Contact information and an interactive map of the majority of participating clinical sites can be viewed under the "Contacts and Locations" section. Please note that the interactive map is not viewable on mobile screens. Related questions and participation interest can be emailed to: flamingo-01@greenwichlifesciences.com

About Breast Cancer and HER2/*neu* Positivity

One in eight U.S. women will develop invasive breast cancer over her lifetime, with approximately 300,000 new breast cancer patients and 4 million breast cancer survivors. HER2 (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 protein, a cell surface receptor protein that is expressed in a variety of common cancers, including expression in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or over-expressor) levels. Greenwich LifeSciences has commenced a Phase III clinical trial, FLAMINGO-01. 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 entitled "Risk Factors" in Greenwich LifeSciences' Annual Report on Form 10-K for the year ended December 31, 2023 and other periodic reports 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.

Company Contact
Snehal Patel
Investor Relations
Office: (832) 819-3232
Email: info@greenwichlifesciences.com

Investor & Public Relations Contact for Greenwich LifeSciences
Dave Gentry
RedChip Companies Inc.
Office: 1-800-RED CHIP (733 2447)
Email: dave@redchip.com

Greenwich LifeSciences

Source: Greenwich LifeSciences, Inc.