February 22, 2024

Greenwich LifeSciences Flamingo-01 Manufacturing & Protocol Accepted by European Regulators

STAFFORD, Texas, Feb. 22, 2024 (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 in patients who have previously undergone surgery, today provided the following update on the expansion of the clinical trial into Europe.

The Company's application to expand Flamingo-01 into Europe has been reviewed by European Medicines Agency (EMA) through EMA's Clinical Trials Information System (CTIS). The Company was informed that the manufacturing, non-clinical, clinical, statistical, and regulatory sections of its application are acceptable and the regulators' requests for information have been addressed. The regulators have thus approved the clinical trial, marking a major milestone for the Company.

The 5 individual countries in Europe will now make a final determination, and if acceptable, they will allow the first group of approximately 105 sites in Europe to begin initiation and activation. Once an individual site has been activated patients can be screened and enrolled.

CEO Snehal Patel commented, "Our interactions with EMA and the 5 participating countries through the CTIS process provided great insight into EMA's expectations for a marketing license application in Europe for GLSI-100. We will continue the dialogue with EMA regulators as we operate Flamingo-01 in Europe, which will help us prepare for an EU licensing application in the future in parallel to filing a BLA in the US."

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/neu 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 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, 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, 2022 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.

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Source: Greenwich LifeSciences, Inc.