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Greenwich LifeSciences Provides Update on Expansion of Flamingo-01 into Spain

STAFFORD, Texas, Aug. 01, 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, today announced the following update of the expansion of clinical sites into Spain.

As previously announced, the Company has partnered with GEICAM, the largest academic breast cancer research network in Spain, where 38 hospitals have agreed to participate in FLAMINGO-01.

To date, approximately 30 out of 38 sites have conducted site initiation visits (SIVs). An SIV is followed by site activation, HLA type screening, and study treatment. To date approximately 19 sites have been activated. Multiples sites have begun screening patients for HLA type and have started treating patients. The Company has visited and trained in-person at approximately 26 out of the 38 sites to ensure optimal treatment at each site. In the coming months, GEICAM hopes to complete the remaining SIVs and the Company hopes to visit the remaining sites.

"It has been an honor to meet with the excellent study staff, investigators and GEICAM staff across Spain. Their expertise and interest in FLAMINGO-01 is encouraging for the success of the study. We look forward to seeing patient recruitment increase in Spain as other countries in the European Union become active," remarked Jaye Thompson, VP of Clinical and Regulatory Affairs.

CEO Snehal Patel commented, "The remarkable progress in Spain, in just May through July, is a testament to the commitment of GEICAM and our team to collaborate and to train the sites together, which we hope will lead to high quality treatment of patients. With just these 30 sites, we have approximately doubled the number of sites that we have opened in the US."

The Company may provide updates on the status of other countries in Europe as the clinical trial is expanded to up to 150 sites in the US, Spain, Italy, France, Germany, and Poland.

About GEICAM

Founded in 1995, GEICAM is a not-for-profit organization leading academic breast cancer research in Spain. It has conducted more than 140 studies involving more than 67,000 women and men and is comprised of more than 900 experts based in over 200 Spanish hospitals. Its mission is to promote independent clinical, epidemiological, and translational research in oncology, with a multidisciplinary approach and under quality criteria, to improve

health outcomes, as well as prevention, medical education, and the dissemination of the knowledge of this disease to patients and general society. More information on GEICAM can be found at https://www.geicam.org/.

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.

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