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Greenwich LifeSciences Announces Addition of City of Hope to FLAMINGO-01

STAFFORD, Texas, March 19, 2026 (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 Fast Track designated GLSI-100, an immunotherapy to prevent breast cancer recurrences, today announced the initiation of new clinical sites in the US.

The Phase III clinical trial has recently been activated at City of Hope, one of the largest and most advanced cancer research and treatment organizations in the United States – specifically at its network sites in Los Angeles and Orange counties, Arizona, Atlanta, and Illinois. Principal investigator at City of Hope, Hope S. Rugo, M.D., continues her participation on the Steering Committee. Her prior site at University of California San Francisco, where she is Professor Emeritus, is still participating in the study.

Dr. Rugo is division chief of breast medical oncology and a professor in the Department of Medical Oncology & Therapeutics Research at City of Hope. She also serves as director of the Women's Cancers Program for City of Hope's national network of cancer centers. A world-renowned expert in breast cancer and clinical trial design and execution, Dr. Rugo oversees women's cancer research initiatives and clinical care at City of Hope. She is focused on expanding breast cancer clinical trials, advancing translational research, and standardizing care to improve patient outcomes. She is deeply committed to improving access to innovative new therapies for breast cancer patients everywhere and takes a compassionate, collaborative approach in her work.

Dr. Rugo has been directly involved in numerous projects that have established new standards of care for breast cancer. She has served on the steering committees of multiple clinical trials that led to the approval of agents such as PARP inhibitors, CDK4/6 inhibitors, PI3K inhibitors, checkpoint inhibitors, and antibody-drug conjugates, among others. Additionally, Dr. Rugo has led several studies aimed at minimizing therapy-related toxicity. She also served as co-chair of the Triple Negative Working Group of the Translational Breast Cancer Research Consortium, where she spearheaded groundbreaking multicenter clinical trials in collaboration with researchers, pharmaceutical companies, and clinical providers. As a physician-scholar with more than 500 peer-reviewed publications, Dr. Rugo served on the editorial board of the American Society of Clinical Oncology's Education Committee, which included co-chairing the creation of new guidelines for the hormonal treatment of metastatic breast cancer.

Dr. Rugo commented, "I am excited to open this important trial across our City of Hope sites, expanding treatment opportunities for our patients with high-risk early stage HER2 positive breast cancer. It is truly an honor to now represent City of Hope on the Steering Committee. This study aligns with City of Hope's interest in and the importance of harnessing the host

immune system to reduce the risk of breast cancer recurrence."

Last year City of Hope launched a national clinical trials model that includes clinical sites across the United States in order to accelerate cancer research.

Dr. Jaye Thompson, VP Clinical and Regulatory Affairs, commented, "We are honored to have Dr. Rugo, a globally recognized leader in breast cancer, now participating in FLAMINGO-01 through her leadership at City of Hope. Her site's expertise and commitment to advancing patient care, which I personally experienced when training these sites, is invaluable as we continue to study GLSI-100. The four City of Hope locations also strengthen our study footprint in some regions of the US where we were not previously covered, providing the study with access to additional population centers."

CEO Snehal Patel commented, "We started working with Dr. Rugo when she was the breast cancer leader at UCSF and joined our Phase III study and Steering Committee. We quickly benefited from her recommendations as the study was starting up and expanding into Europe. Her extensive experience in developing novel therapies, while minimizing toxicities, will guide us through the development of GLSI-100 as an effective and safe vaccine to prevent metastatic breast cancer in high-risk breast cancer survivors. With the addition of these new sites at City of Hope, planned expansion of US Oncology/Sarah Cannon sites, addition of sites in new countries, including potentially the United Kingdom and Canada, the total sites participating in FLAMINGO-01 could increase from the current 160 sites to up to 190-200 sites."

About FLAMINGO-01 Open Label Phase III Data

More than 1,000 patients have been screened with a current screen rate of approximately 800 patients per year. The 250 patient non-HLA-A*02 arm is now fully enrolled, where all patients received GLSI-100, which is 5 times more treated patients and recurrence rate data than the approximately 50 patients treated in the Phase IIb trial. The Primary Immunization Series (PIS), which includes the first 6 GLSI-100 injections over the first 6 months and is required to reach peak protection, is followed by 5 booster injections given every 6 months to prolong the immune response, thereby providing longer-term protection.

- In the non-HLA-A*02 arm, a preliminary analysis of recurrence rates after the PIS is completed shows an approximately 70-80% reduction in recurrence rate.
- This observation is trending similarly to the Phase IIb trial results and hazard ratio where HLA-A*02 patients were treated and where breast cancer recurrences were reduced up to 80% compared to a 20-50% reduction in recurrence rate by other approved products.
- The immune response at baseline prior to any GLSI-100 treatment, the increasing immune response during the PIS, and the safety profile of non-HLA-A*02 patients is trending similarly to the HLA-A*02 arms of FLAMINGO-01 and to the Phase IIb study.

Analysis of the open label data from FLAMINGO-01 has been conducted in a manner that maintains the study blind. The open label recurrence rate, immune response, and safety data is based on the patients enrolled to date in FLAMINGO-01 and the data provided by the

clinical sites so far, which is not completed or fully reviewed, and is thus preliminary. While comparing any preliminary FLAMINGO-01 data to the Phase IIb clinical trial data may be possible, these preliminary results are not a prediction of future results, and the results at the end of the study may differ.

About GLSI-100 Phase IIb Study

In the prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites led by MD Anderson Cancer Center) Phase IIb clinical trial of HLA-A*02 breast cancer patients, 46 HER2/neu 3+ over-expressor patients were treated with GLSI-100, and 50 placebo patients were treated with GM-CSF alone. After 5 years of follow-up, there was an 80% or greater reduction in cancer recurrences in the HER2/neu 3+ patients who were treated with GLSI-100, followed, and remained disease free over the first 6 months, which we believe is the time required to reach peak immunity and thus maximum efficacy and protection. The Phase IIb results can be summarized as follows:

- 80% or greater reduction in metastatic breast cancer recurrence rate over 5 years of follow-up with a peak immune response at 6 months and well-tolerated safety profile.
- The PIS elicited a potent immune response as measured by local skin tests and immunological assays.

About FLAMINGO-01 and GLSI-100

FLAMINGO-01 (NCT05232916) is a Phase III clinical trial designed to evaluate the safety and efficacy of Fast Track designated 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 and European clinical sites from university-based hospitals and academic and cooperative networks with plans to open up to 150 sites globally. In the double-blinded arms of the Phase III trial, approximately 500 HLA-A*02 patients are planned to be randomized to GLSI-100 or placebo, and up to 250 patients of other HLA types are planned to 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 the most recent Form 10-K for the year ended December 31, 2024, 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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