December 8, 2025

Greenwich LifeSciences Announces Completion of Enrollment in the Open Label Arm of FLAMINGO-01

STAFFORD, Texas, Dec. 08, 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 announced the completion of enrollment in the open label non-HLA-A*02 arm of FLAMINGO-01.

In the double-blinded arms of the Phase III trial, approximately 500 HLA-A*02 patients are currently planned to be randomized to GLSI-100 or placebo, and up to 250 patients of other HLA types (non-HLA-A*02) are planned to be treated with GLSI-100 in a third open label arm. The non-HLA-A*02 patients do not have the HLA-A*02 allele from either parent and represent about 55% of the patient population in FLAMINGO-01.

- FLAMINGO-01 has achieved a major milestone by completing enrollment in the 250 patient open label non-HLA-A*02 arm of the Phase III trial, which is a result of the high screen rate and ensuing enrollment rate. The Company is continuing its review of the most recent data of this arm, including recurrence rates, which can be updated and/or published at any time.
- The Company stopped enrolling in this arm earlier this year and is now approaching regulatory agencies to seek approval to continue enrollment of new non-HLA-A*02 patients in a randomized manner with a control arm. The Company has continued to screen a large number of these patients so that rapid enrollment of these screened patients can commence if regulatory approval is received.
- The Company previously reported promising observations earlier this year showing that the immune response at baseline prior to any GLSI-100 treatment, the increasing immune response during the primary immunization series, 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, where breast cancer recurrences were reduced up to 80% or more and no metastatic breast cancer recurrences were reported. A preliminary analysis suggests that these promising trends are continuing.

CEO Snehal Patel commented, "As we continue to analyze the immune response, safety, and recurrence rate data of the 250 patient non-HLA-A*02 data set, it is important to remember that all 250 patients received GLSI-100, which is 5 times more than the approximately 50 patients treated in the Phase IIb trial. We can compare the open label recurrence rate data of these 250 treated patients to the expected historical recurrence rate for this population, which is well known and recently reported, to the HLA-A*02 arms of

FLAMINGO-01, and to the Phase IIb study. In addition, we may be able to compare the recurrence rate during the first 6 months of vaccination, also called the primary immunization series or PIS, to the recurrence rate after the PIS is completed and after peak immunity is achieved. We look forward to providing updates on this analysis at any time, including publications at conferences as we have previously done for the Phase IIb trial from 2020-2022."

Mr. Patel added, "The use of GLSI-100 in the non-HLA-A*02 patient population is an invention by the Company, and the Company believes that any patent claims related to this invention are not subject to any license, royalties, or milestone payments. These patent claims should complement other patent claims that the Company has recently filed to potentially extend patent protection of GLSI-100 beyond 2040. The Company believes that this patient population could double the number of US and European patients eligible for GLSI-100 treatment to approximately 88,000 new patients per year with a market potential using the drug prices per year of Kadcyla or Enhertu in the range of $8-10 billion per year."

Additional updates:

- The non-HLA-A*02 types that are most commonly being enrolled in FLAMINGO-01 continue to be HLA-A*03, HLA-A*24, HLA-A*01, HLA-A*11, HLA-A*68, HLA-A*29, HLA-A*30, HLA-A*23, and HLA-A*33.
- The enrollment of HLA-A*02 patients in the 500 patient randomized arms continues, unaffected by the end of enrollment in the non-HLA-A*02 arm, while the Company also seeks to increase the size of these HLA-A*02 arms such that enrollment is not stopped prior to any interim analyses.
- Enhertu (trastuzumab Deruxtecan [T-DXd]) treated patients continue to be eligible for enrollment in FLAMINGO-01. The Company believes that GLSI-100 will synergize with any trastuzumab based treatment in the neoadjuvant or adjuvant settings, including Enhertu.

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 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 website[here](here) 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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Source: Greenwich LifeSciences, Inc.