December 22, 2025

Greenwich LifeSciences Provides Additional Updates on FLAMINGO-01 and Corporate Strategy

STAFFORD, Texas, Dec. 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 Fast Track designated GLSI-100, an immunotherapy to prevent breast cancer recurrences, today provided additional updates on FLAMINGO-01 and the Company's corporate strategy.

Corporate Strategy

The Company recently attended a Noble Capital conference on December 3, 2025, where further details of the Company's FLAMINGO-01 clinical strategy, financing strategy, and partnering strategy were discussed in a fireside chat with the Noble analyst. The video is now available on the Company's website at the bottom of the Welcome page: https://greenwichlifesciences.com/

Below are highlights from the discussion with additional information:

- Clinical strategy – The FLAMINGO-01 clinical strategy continues to evolve with various options to further reduce risk and increase the chances of marketing approval supported by the current financing strategy that is supporting the current burn rate, the increasing interest from investigators and patients, cost reduction activities, and continued interest to add additional sites and countries to the study.
    - Approximately 140 sites are actively enrolling patients, and there are plans to activate an additional 10 already approved sites in 2026 and additional EU countries.
    - Quality improvement and cost reduction may be realized by moving more clinical trial operations internally and ending the use of a CRO for the US operations and global management.
    - The study has transitioned from strong interest from principal investigators to patient driven interest, including the formation of wait lists at certain sites.
    - The Company has entered into discussions with leading clinical sites in the United Kingdom and Canada regarding joining the study, which would require regulatory approval in each country, independent from the FDA and EMA regulatory approval that the Company has already received.

- Financing strategy – The ATM financing is being used judiciously and efficiently to keep up with the burn rate in 2025, potentially exceeding the burn rate by year end. This ATM strategy reduces the likelihood of the Company doing a near term financing, increasing the chances for non-dilutive strategic partnerships at any time before or after an interim analysis.

    - The Company's annual burn rate was approximately $7 million in 2024 and 2023. The income statements for these periods have been reported as losses of $16 million and $9 million respectively, but the cash flow used for operations is much lower at $7 million due to the non-cash stock and options expenses added to the income statements.

    - For the first three quarters of 2025, the burn rate is approximately $7 million, representing a gradual increase in burn rate over 2024, but not a substantial increase due to the Company's lean structure and ongoing cost saving initiatives. In addition, a large part of the clinical expenses is from the upfront costs and the first 6 months of monthly vaccinations or Primary Immunization Series, after which the cost per patient should be lower when boosters are given once every 6 months.

- Partnering strategy – The Company continues to attend partnering conferences.

    - Large pharma dominates the breast cancer drug market, including acquiring or partnering with smaller biotechs who have promising new breast cancer drugs.

    - We believe patent filings for treating non-HLA-A*02 patients with GLSI-100 will strengthen the patent portfolio for GLSI-100, in addition to the biologics data exclusivity available to GLSI-100 in the US.

FLAMINGO-01 Data Safety Monitoring Board (DSMB) & Steering Committee

The FLAMINGO-01 DSMB met twice in 2025, most recently in December 2025, and recommended to continue the study as is without modification. The Steering Committee also met at SABCS 2025 and discussed the clinical strategy, endorsing the planned modifications to FLAMINGO-01. The planned modifications subject to regulatory approval include:

- increasing the size of the study, which would increase the power of the study thus decreasing the risk by designing the study to assume more recurrences even though fewer recurrences may be anticipated and observed,

- doubling or quadrupling the enrollment rate, which will increase the patient years in the study more rapidly thus proportionately increase the event rate, which may shorten the time to reach an interim analysis or milestone,

- continuing to enroll past the interim analyses so that the current momentum at the clinical sites continues,

- using the interim analysis to potentially resize the study or to change the subsequent interim analysis, to change the number of events triggering an analysis, or to change the timing of the study based on recommendations by an independent committee, and

- using a recently manufactured GP2 commercial drug product lot in FLAMINGO-01

CEO Snehal Patel commented, "We are looking forward to continuing our financing strategy and implementing the planned Phase III trial derisking modifications, pending regulatory approvals. The discussions with clinicians at SABCS 2025 were encouraging, as the study has become more widely recognized by the breast cancer community, leading to patient and investigator driven interest to expand FLAMINGO-01 into the United Kingdom and Canada. The potential for GLSI-100 to save lives by preventing metastatic breast cancer recurrences and thus reduce overall healthcare costs was also highlighted at the Noble conference. The open label data of FLAMINGO-01 in the non-HLA-A*02 arm has helped to increase the probability of success, while potentially doubling the market for GLSI-100, and will continue to be analyzed as we may provide updates or publications at any time."

About FLAMINGO-01 Open Label Phase III Data

More than 1,000 patients have been screened with a current screen rate of approximately 600 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 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 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.

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.