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Greenwich LifeSciences Provides Clinical Updates on FLAMINGO-01

STAFFORD, Texas, July 20, 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 GLSI-100, an immunotherapy to prevent breast cancer recurrences, today provided the following clinical updates on FLAMINGO-01.

FLAMINGO-01 Data Safety Monitoring Board (DSMB)

The FLAMINGO-01 DSMB met in May 2026 and recommended the study continue as is without modification.

FLAMINGO-01 Steering Committee Clinical Strategy

On December 22, 2025, the company announced the following objectives:

"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 pleased to announce that following review by FDA and EMA regulatory authorities that these objectives have been met and that FLAMINGO-01 now has the hallmarks of a large pharma Phase III clinical trial. The study is now designed

and sized to improve the probability of success, to attract the interest of sophisticated investors and pharma companies, and to maximize the chances that the Company could file a BLA after interim analysis 1, after interim analysis 2, or after the end of the study."

Mr. Patel further added, "The transition is now underway globally at all sites. We have provided below in this press release the details of the study design reviewed by both the US and EU agencies, and currently subject to review by the UK and Canada, and will be updating the Company website and presentation, www.ClinicalTrials.gov, and videos accordingly. These agencies may provide additional recommendations or requirements at any time and we remain flexible to accommodate their advice as needed."

The Company plans to now leverage the increased enrollment rate resulting from the combination of all HLA types together with the following: 1) the very high interest from patients and clinicians which has led to almost 200 clinical trial sites in the US and Europe, 2) the clinical operational capability in place 3) the currently trending low event rate, and 4) the efficient cost structure and burn rate that the Company has successfully funded through small capital raises.

Enrollment Rate into the Blinded Arm

As previously disclosed, all European and US Sites will combine all new patients independent of HLA type in the randomized arms of FLAMINGO-01. Non-HLA-A*02 patients who represent about 55% of the population and were on waiting lists for up to a year are now eligible for enrollment, which could provide for the rapid enrollment of up to 300 patients. This protocol amendment will more than double the enrollment rate increasing it by 122% or resulting in a 2.22x faster enrollment rate (55%/45% = 122%), which proportionately increases the event rate. This more than doubling of the event rate, provides an opportunity to derisk the study and provide multiple pathways to filing a BLA in the US with much higher probabilities of success at each opportunity for analysis.

Leveraging the High Interest from Patients and Clinicians

The Company has achieved a major milestone by screening over 1,500 patients in Flamingo-01, continuing its screening rate of approximately 150-200 patients per quarter or the equivalent of 600-800 patients per year in approximately 170-180 sites.

The 11 participating countries include: US, Spain, France, Germany, Italy, Poland, Romania, Ireland, Portugal, Belgium, and Austria. The Company is planning to add the following additional European countries due to interest from principal investigators and patients: Norway, Denmark, and Sweden in addition to the UK and Canada.

Rationale to Keep Enrollment Open Until Interim Analyses

In the double-blinded arms of the Phase III trial, the originally designed 500 HLA-A*02 patients were likely to be filled before the interim analysis and thus the clinical sites would have had to stop enrolling. If the interim analysis suggested that more patients should be enrolled, restarting enrollment would have been very difficult. A 2.22x increase in the enrollment rate without any other modifications would have accelerated the stopping of enrollment, but the probability of a successful data analysis at the interim analysis and the filing of BLA would not be increased. It isn't in the study's best interest to wait for more

events without the option to continue enrolling to increase the event rate. It is optimal to keep enrolling while collecting events because even patients in the study for only a short time are at risk of recurrence and can add information to analyses.

Capital Raising Strategy Has Kept up with Modestly Increasing Burn Rate

The cash burn will be manageable as in the past due to the efficiently run and internalized clinical operations. The manufacturing of GP2 vials for the Phase III clinical trial has been completed with sufficient vials to treat all patients. Most of the start-up costs for the clinical sites have been paid. Many patients have entered the booster phase with 2 vaccinations per year with lower costs thus offsetting the higher costs for patients entering the study, when 6 vaccinations in the first 6 months during the primary immunization series are required.

The Company's annual burn rate was approximately $7 million in 2024 and 2023 and $10 million in 2025. The income statements for these periods have been reported as much higher losses, but the cash flow used for operations is much lower due to the non-cash stock and options expenses added to the income statements.

For the second quarter of 2026, the burn rate is expected to be approximately $2 million versus a $4.7 million burn rate in the first quarter of 2026, leading to a Q2 2026 cash balance of approximately $8.9 million as of June 30, 2026 and an expected burn rate of $2-4 million per quarter going forward. The above preliminary financial figures are unaudited and are subject to change following completion of the Company's financial review for Q2 2026. This capital raising strategy may provide a bridge to non-dilutive funding, such as strategic/licensing partnerships or debt/royalty financing vehicles, that would further fund FLAMINGO-01 and potential commercial launch activities.

Improved Trial Design Allows for Substantial Reduction in Risk

In the double-blinded arms of the Phase III trial, the trial has been designed to detect a hazard ratio (HR) of 0.55 in invasive breast cancer-free survival, where 28 events will be required for the 1st interim analysis, 56 events will be required for the 2nd interim analysis, and 133 events will be required to end the study. Interim analyses for superiority and futility will be conducted and, if successful, could lead to the filing of a BLA in the US at those times. The number of patients enrolled in the study will depend on the event rate and thus enrollment may continue for as long as necessary up to a maximum of 2,000 patients. This sample size provides 80% power if the annual rate of events in placebo-treated subjects is 2.4% or greater and the HR is 0.55. In addition, the number of events may be adapted by the DSMB based on interim analyses.

By doubling the number of events to trigger an interim and increasing the HR, which is offset by the more than doubling event rate due to the higher enrollment rate, and may or may not alter time lines, the probability of a positive study outcome can be increased substantially. An increase of the HR puts FLAMINGO-01 more in line with other prominent large pharma breast cancer Phase III clinical trials such as Katherine for Kadcyla and Destiny Breast-05 for Enhertu. The HR is equal to one minus the percent reduction in events caused by the treatment arm. For example, an HR = 0.3 would suggest a 70% reduction in events and an HR = 0.75 would suggest a 25% reduction in events by the treatment arm.

The Katherine study which compared Kadcyla to Herceptin breast cancer treatment in the

adjuvant setting after surgery in the residual disease population assumed a design HR = 0.75 but realized a lower study result HR at the first interim of 0.5, which led to a sufficiently low p value and strong enough statistical significance to warrant approval for Kadcyla in the adjuvant setting following submission of interim data to the FDA. Approximately 1,486 patients were enrolled, 256 events were observed at the interim analysis, and 385 events were observed at the final analysis.

The Destiny Breast-05 study which compared Enhertu to Kadcyla breast cancer treatment in the adjuvant setting after surgery, in a higher risk residual disease population than Katherine, assumed a design HR = 0.675 but realized a lower study result HR at the first interim of 0.5, which led to a sufficiently low p value and strong enough statistical significance to warrant approval for Enhertu in the adjuvant setting following submission of interim data to the FDA. Approximately 1,635 patients were enrolled and 153 events were observed at the interim analysis.

GLSI-100 by contrast has shown a study result HR = 0.2 in the Phase IIb clinical trial for HLA-A*02 patients. In the 250 patient non-HLA-A*02 open label arm of FLAMINGO-01, which is now fully enrolled and where all patients received GLSI-100, a preliminary analysis of recurrence rates after the PIS is completed shows an approximately 70-80% reduction in recurrence rate or a HR = 0.2-0.3 when calculated by various methods. This data is early and will continue to mature over time. This low event rate is supported by immune response data that was recently published at AACR and ASCO conferences in 2026. The section below, "About FLAMINGO-01 Open Label Phase III Data", summarizes these results and provides links to the posters at the conferences.

By increasing the original FLAMINGO-01 trial design HR = 0.3 to a design HR = 0.55 and by doubling the events required to trigger the first interim analysis from 14 to 28 events, the probability of success or power at the first interim analysis, if a lower study result HR = 0.3 is realized, increases from less than 20% to more than 85%. This increase in power at the first interim, when the study result HR is lower than the design HR, is possible due to the combination of both HLA types, while the more than double event rate at 2.22x offsets the doubling of the events required to trigger this first interim analysis. Effectively increasing the probability of filing a BLA at the first interim analysis from 20% to 85% justifies the study design changes.

Additional benefits of the new design include:

- The first interim results may affect or alter the design of the second interim.
- Endpoints can be analyzed by individual HLA types as well as one combined group of all HLA types and given that each patient has 2 HLA-A alleles, one from each parent, there are multiple analyses that can be conducted.
- Doubling the market for GLSI-100 to potentially $10 billion in revenue per year by accelerating the clinical development of the non-HLA-A*02 population.
- Capital raise requirements are still modest, based on the Company's disciplined operations and low burn rate.

About FLAMINGO-01 Open Label Phase III Data

More than 1,500 patients have been screened at a screen rate of approximately 600-800 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.
- The non-HLA-A*02 arm 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.
    - The AACR Meeting 2026 delayed-type-hypersensitivity (DTH) poster and the ASCO Meeting 2026 injection site reaction (ISR) poster can be seen and downloaded at the bottom of the Phase III clinical trial tab on the Company's website here.
    - As shown in both posters the frequency of DTH and ISR reactions increased statistically significantly over time.
    - As reported in Table 1 of each poster, each HLA-A type exhibited more frequent immune reactivity after treatment with GLSI-100 than at baseline.
    - Baseline DTH reaction prior to any treatment suggests that GP2 may be a natural antigen and that GP2 specific T cells may exist in some patients prior to any treatment with GLSI-100. Baseline immune response to GP2 prior to any vaccination with GP2 was also observed in the Phase IIb trial and is being observed in the blinded randomized arms of FLAMINGO-01, where HLA-A*02 only patients are being vaccinated.

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 posters and results can be summarized as follows and can be seen here:

- 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 170-180 sites globally.

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. In the US and Europe, there are approximately 700,000 new breast cancer patients per year and 9.5 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, 2025, 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

Source: Greenwich LifeSciences, Inc.