June 1, 2026

Greenwich LifeSciences Provides Update Regarding Form 10-K Filing

STAFFORD, Texas, June 01, 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 provided an update on its Form 10-K filing for the fiscal year ending December 31, 2025.

The Form 10-K for the fiscal year ending December 31, 2025, continues to be audited by our new auditor and we believe it is in the final approval steps. The Form 10-K also includes the 2024 audit that was previously audited by the prior auditor. As previously indicated, the accounts payable adjustments are related to the large global Phase III clinical trial underway and the unexpectedly large increase in screening and patient enrollment in Europe in 2024 and 2025. Both auditors in a dual auditor filing must agree in order to make timely filings, which did not occur in March or April, and such coordination is still required as part of the final approval steps.

The Company believes that it did not contribute to the delays in filing and instead did everything possible to file on time. The Company provided the 10K filing information with large increases to accounts payable to the auditors for review in early February 2026 and requested and anticipated an early filing. The Company has further improved its accounts payable estimations using current clinical trial data in its financials for Form 10-Q for the period ending March 31, 2026.

The Company believes that the accounts payable adjustments are not material to the Company or its investors and does not change the fundamentals of the Company. The shift in expenses does not change the cash balance or the net cash used in operating activities of the Company. As previously announced, the Company's ending cash balance as of March 31, 2026 is approximately $10.5 million, which the Company believes is an improvement over 2025 ending cash balances, and includes the retirement of over 75% of accounts payable for the fiscal year ending December 31, 2025. This $10.5 million cash balance is more than the 2025 net cash used in operating activities which is approximately $9.9 million. The above figures are unaudited and are subject to change following the completion of the Company's financial audit for the year ending December 31, 2025 and the review for the period ending March 31, 2026.

About FLAMINGO-01 Open Label Phase III Data

More than 1,300 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.
    - The AACR Meeting 2026 delayed-type-hypersensitivity (DTH) poster can be downloaded here.
    - The frequency of DTH reactions increased by approximately 4x (290%) in the total open-label non-HLA-A*02 population, increasing from 5.2% of the patients experiencing a DTH reaction at baseline, prior to any GLSI-100 administration, to 20.4% of the patients experiencing a DTH reaction in month 4 or month 6 (McNemar, $p < 0.001$).
    - As reported in Table 1 of the poster, each HLA-A type exhibited more frequent immune reactivity after treatment with GLSI-100 than at baseline with frequency increasing from 100% to 700%.
    - 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 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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