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Greenwich LifeSciences Presents FLAMINGO-01 Phase III Trial Open Label Data Published at ASCO Meeting 2026

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 presents the published abstract and poster from the ASCO Annual Meeting 2026.

The abstract is shown below and the poster being presented today can be seen and downloaded at the bottom of the Phase III clinical trial tab on the Company's website here.

- This is the second abstract and poster presented jointly with the Steering Committee of FLAMINGO-01 with statistically significant injection site reaction (ISR) immune response data, with subgroup analysis by the most prevalent HLA types.

- In the non-HLA-A*02 open label arm where all patients (n=247) were treated with GLSI-100, immune responses to GP2 were measured at baseline and over time using skin tests (DTH) and ISRs.

- An ISR reaction, erythema (redness) or induration (white hard bump), was used to assess in vivo immune responses in patients. The diameter of the reaction was assessed 48-72 hours after injection but is not reported here.

- In this preliminary data analysis, there was a significant increase in percentage of patients experiencing an ISR reaction (for both erythema and induration) in vaccination 4, vaccination 5 or vaccination 6 compared to the baseline vaccination. There were 208 patients with both baseline vaccination and vaccination 4, 5 or 6 assessments.

- Erythema: There was a significant increase in the percentage of patients experiencing erythema ISRs after the 4th, 5th or 6th vaccination compared to the ISRs from the 1st vaccination. In this preliminary analysis, the frequency of ISRs increased significantly from 20.2% of the patients experiencing an ISR after the first vaccination to 55.3% of the patients experiencing an ISR after the 4th, 5th or 6th vaccination (McNemar $p < 0.001$), representing an increase of 2.7x or 174%.

- Induration: There was a significant increase in the percentage of patients experiencing induration ISRs after the 4th, 5th or 6th vaccination compared to the ISRs from the 1st vaccination. In this preliminary analysis, the frequency of ISRs increased significantly from 14.9% of the patients experiencing an ISR after the first vaccination to 34.6% of the patients experiencing an ISR after the 4th, 5th or 6th vaccination (McNemar p <

0.001), representing an increase of 2.3x or 132%.

- As reported in Table 1, each HLA-A type exhibited more frequent immune reactivity with increased GLSI-100 vaccinations with frequency increasing by 60% to 280% over the frequency after the first vaccination. These results are consistent with the GP2 DTH results presented at AACR.

- Mechanism of Action: A positive immune response is an indicator that the immune system has been activated against recurring cancer cells, potentially leading to the prevention of metastatic breast cancer. The Company previously announced that in the non-HLA-A*02 arm, a preliminary analysis of recurrence rates after the Primary Immunization Series (PIS) is completed shows an approximately 70-80% reduction in recurrence rate. Thus, the immune response data is supporting the mechanism of action that reduces recurrences and prevents metastatic breast cancer.

- This statistically significant non-HLA-A*02 open label arm immune response data for both DTH and ISRs is trending similarly to the immune response data in the HLA-A*02 patients in the Phase IIb study and the HLA-A*02 arms of FLAMINGO-01. The study is ongoing and data collection and cleaning continue, while some patients may still be in their PIS vaccination phase, so final results may vary.

The immune response abstract and poster conclusion: The statistically significant increase in the incidence of ISR reactions over time found in this preliminary analysis of GLSI-100 treated non-HLA-A*02 patients shows that GLSI-100 treatment should not be limited to HLA-A*02 patients. Patients treated with GLSI-100 were increasingly able to mount an immune response to GP2 as evidenced in this preliminary data. Future investigations may explore the use of immune responses to assess correlation of DTH to ISRs, immunogenicity of GLSI-100 by specific HLA type, timing of boosters to sustain immunity, clinical site performance, and the discontinuation of treatment for non-responders.

CEO Snehal Patel commented, "The DTH immune response data presented at AACR and the ISR immune response data presented today together further support the mechanism of action and the combination of HLA-A*02 and non-HLA-A*02 patients in the same randomized arms, potentially improving the chances of success at the interim analysis and more than doubling the market potential for GLSI-100. This combination of patients, independent of HLA type, has already started in the US and may soon start in Europe. In addition to ASCO, the Company previously attended AACR and ESMO Breast and plans to attend BIO partnering and investor conferences in the coming months, while presenting additional FLAMINGO-01 data at any time."

The abstract from today's immune response data and the members of the Steering Committee follow:

Abstract Number: LBA538 - Poster Section 23 on June 1, 2026, 1:30 - 4:30pm CT

Abstract Title: Preliminary injection site reaction immune response results from open-label arm of on-going Phase III study to evaluate the efficacy and safety of GLSI-100 (GP2 + GM-CSF) in breast cancer patients with residual disease or high-risk PCR after both neo-adjuvant and postoperative adjuvant anti-HER2 therapy, Flamingo-01

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Background: This Phase III trial is a prospective, randomized, double-blinded, multi-center study (*NCT05232916*) in HLA-A*02 patients at approximately 140 sites in the US and Europe. A third non-randomized arm of approximately 250 non-HLA-A*02 patients is now fully enrolled and preliminary immune response data is presented below. GP2 is a biologic nine amino acid peptide of the HER2/*neu* protein delivered in combination with Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) that stimulates an immune response targeting HER2/neu expressing cancers, the combination known as GLSI-100.

Methods: After standard of care neoadjuvant and adjuvant therapy, 6 intradermal injections of GLSI-100 will be administered over the first 6 months and 5 subsequent boosters will be administered over the next 2.5 years. The participant duration of the trial will be 3 years treatment plus 1 additional year follow-up. Immune responses to GP2 were measured over time using delayed-type-hypersensitivity (DTH) skin tests and injection site reactions (ISRs). The patient population is defined by these key eligibility criteria: 1) HER2/neu positive and HLA, 2) Residual disease or High risk pCR (Stage III at presentation) post neo-adjuvant therapy, 3) Exclude Stage IV, and 4) Completed at least 90% of planned adjuvant trastuzumab-based therapy.

Results: All patients (n=247) were vaccinated with GLSI-100. Injection site reactions, erythema (redness) was assessed at various time points and represent an in vivo immune response in patients. The ISR orthogonal mean was measured 48-72 hours following vaccination with GLSI-100. For GP2 treated patients, there was a significant increase in the percentage of patients experiencing ISRs in the 4^{th}, 5^{th} or 6^{th} vaccination compared to the ISRs from the 1st vaccination. In this preliminary analysis, the frequency of ISRs increased significantly from 20.2% of the patients experiencing an ISR after the first vaccination to 55.3% of the patients experiencing an ISR after the 4^{th}, 5^{th} or 6^{th} vaccination (McNemar $p < 0.001$). The study is ongoing and data collection and cleaning continue so final results may vary.

Conclusions: Preliminary injection site reaction data comparing vaccination over time in GLSI-100 treated non-HLA-A*02 patients showed a significant increase in immune response. Future studies may explore the use of immune responses to assess: correlation of DTH to ISRs, immunogenicity of GLSI-100 by specific HLA type, timing of boosters to sustain immunity, clinical site performance, and the discontinuation of treatment for non-responders.

The Steering Committee authoring abstract LBA538 is comprised of the following experts in

the field of breast cancer oncology representing prominent teaching hospitals in the US and 4 of the largest breast oncology networks in the US, Germany, France, and Spain:

- **Dr. Mothaffar F. Rimawi** – Professor of Medicine at the Baylor College of Medicine and Executive Medical Director and Co-Leader, Breast Cancer Program of the Dan L Duncan Comprehensive Cancer Center
- **Dr. Francois-Clement Bidard** – Professor of Medical Oncology, UVSQ/Paris Saclay University, Head of Breast Cancer Group, Institut Curie, Vice-Chair of the French Breast Cancer research group UCBG (Unicancer)
- **Dr. William J. Gradishar** – Professor of Medicine at the Feinberg School of Medicine at Northwestern University, Chief of Hematology and Oncology in the Department of Medicine, and Betsy Bramsen Professor of Breast Oncology
- **Dr. Sibylle Loibl** – Professor (apl) Goethe University Frankfurt/M, Clinical Consultant Centre for Haematology and Oncology/Bethanien Frankfurt/M, CEO of GBG Forschungs GmbH & Chair of the German Breast Group (GBG)
- **Dr. Miguel Martin** – Professor of Medicine, Head, Medical Oncology Service, Gregorio Marañón General University Hospital, Complutense University, Madrid, CEO of GEICAM
- **Dr. Joyce A. O'Shaughnessy** – Celebrating Women Chair in Breast Cancer, Baylor University Medical Center and Chair, Breast Cancer Program, Texas Oncology, US Oncology, Dallas, Texas
- **Dr. Hope S. Rugo** – Director, Women's Cancers Program, Division Chief, Breast Medical Oncology, Professor, Department of Medical Oncology & Therapeutics Research, City of Hope Comprehensive Cancer Center, Professor Emeritus, University of California, San Francisco
- **Dr. Cesar A. Santa-Maria** – Associate Professor of Oncology, Breast and Gynecological Malignancies Group, Director of Breast Cancer Trials, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
- **Dr. Laura M. Spring** – Assistant Professor, Medicine, Harvard Medical School, Attending Physician, Medical Oncology, Massachusetts General Hospital

About the 2026 ASCO Annual Meeting

ASCO is the world's leading professional organization for physicians and oncology professionals caring for people with cancer. ASCO offers premier scientific events for oncology professionals, patient advocates, industry representatives, and major media outlets worldwide. The ASCO Annual Meeting program features poster presentations, poster discussion sessions, clinical science symposia, and dynamic education sessions about recent advancements in cancer research, treatment, and patient care. For more information, please visit the conference website at: https://conferences.asco.org/am/attend.

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 and the ASCO Meeting 2026 injection site reaction (ISR) posters 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 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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