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

STAFFORD, Texas, April 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 Fast Track designated GLSI-100, an immunotherapy to prevent breast cancer recurrences, today presents the published abstract and poster from the AACR Meeting 2026.

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

- This is the first abstract and poster presented jointly with the Steering Committee of FLAMINGO-01 with statistically significant delayed-type-hypersensitivity (DTH) 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 and other methods. The other methods will be presented at a future conference.
- A DTH reaction (redness and/or induration) was used to assess in vivo immune responses in patients. The DTH orthogonal mean was also measured 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 a DTH reaction (redness) in month 4 or month 6 compared to baseline. There were 191 patients with both baseline and month 4 or 6 assessments.
- 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.

- 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 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.

- A 1% per year recurrence rate is so low that the number of recurrence events is too few to correlate a negative or lack of immune response to recurrence. The same constraint existed with the Phase IIb data which has a similarly low recurrence rate per year. While DTH immune response may be valuable at an aggregate level looking at whole patient populations, the recurrence rate is too low to validate any immune response measure as a biomarker for individual patient treatment decisions. It is also likely that some responding patients may not exhibit any immune response but still could be protected by GLSI-100 vaccination, thus helping to preserve the blind on the randomized arms of FLAMINGO-01.

The immune response abstract and poster conclusion: The statistically significant increase in the incidence of DTH 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.

In addition, the second poster describing the Phase III trial design, which is being presented on Tuesday, April 21, can be downloaded and seen on the website using the same link. This poster provides an update that over 1,300 patients have been screened to date in FLAMINGO-01. The new protocol amendment, which is still under regulatory review in certain countries, is not discussed.

CEO Snehal Patel commented, "This new immune response data further supports the combination of HLA-A*02 and non-HLA-A*02 patients in the same randomized arms. In the US, the FDA recently reviewed such protocol changes and the many non-HLA-A*02 patients on waiting lists that were previously screened are now being enrolled. The screen rate continues to be encouraging, reflecting the high patient interest in the study as we have now

screened over 1,300 patients. The Company will have the option to pursue approval for both HLA-A*02 and non-HLA-A*02 patients together using the increased statistical power of a combined analysis of the two patient groups or to pursue subgroups based on planned multiple interim analyses."

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

Abstract Number: CT138 - Poster Section 52 on April 20, 2026, 2-5pm PT

Abstract Title: Preliminary delayed-type-hypersensitivity 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 trastuzumab-based therapy.

Results: All patients (n=247) were vaccinated with GLSI-100 and continue in treatment and follow-up. A DTH reaction (redness) was used to assess in vivo immune responses in patients. The DTH orthogonal mean was measured 48-72 hours after injection. In this preliminary data analysis, there was a significant increase in percentage of subjects

experiencing a DTH reaction in month 4 or month 6 compared to baseline. The frequency of DTH reactions increased by approximately 4x 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, $p < 0.001$). The study is ongoing and data collection and cleaning continue so final results may vary.

Conclusions: The increase in the incidence of DTH 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 the HLA-A*02 genotype. Subjects 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.

The Steering Committee authoring abstract CT138 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 AACR Annual Meeting 2026

The AACR is the first and largest cancer research organization dedicated to accelerating the conquest of cancer and has more than 61,000 members residing in 143 countries and territories. The AACR Annual Meeting is the focal point of the cancer research community, where scientists, clinicians, other health care professionals, survivors, patients, and advocates gather to share the latest advances in cancer science and medicine. From population science and prevention; to cancer biology, translational, and clinical studies; to survivorship and advocacy; the AACR Annual Meeting highlights the work of the best minds in cancer research from institutions all over the world.

About FLAMINGO-01 Open Label Phase III Data
More than 1,000 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.

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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