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# Greenwich LifeSciences Provides Update on Upcoming AACR Meeting

STAFFORD, Texas, March 18, 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 the upcoming AACR Meeting 2026.

Two abstracts and two posters were accepted for presentation. The titles and authors of the abstracts are as follows:

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

**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

Snehal S. Patel<sup>1</sup>, Jaye Thompson<sup>1</sup>, F. Joseph Daugherty<sup>1</sup>, Francois-Clement Bidard<sup>2</sup>, William J. Gradishar<sup>3</sup>, Marcus Schmidt<sup>4</sup>, Miguel Martin<sup>5</sup>, Joyce A. O'Shaughnessy<sup>6</sup>, Hope S. Rugo<sup>7</sup>, Cesar A. Santa-Maria<sup>8</sup>, Laura M. Spring<sup>9</sup>, Mothaffar F. Rimawi<sup>10</sup>

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- This will be the first abstract and poster from FLAMINGO-01 with statistically significant immune response data, potentially with subgroup analysis by the most prevalent HLA types. 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 and improved long term survival.
- Immune responses to GP2 were measured at baseline and over time using delayed-type-hypersensitivity (DTH) skin tests and other methods. The DTH skin test measures the diameter of the skin immune response to GP2 in millimeters, 48-72 hours after intradermal injection of a low concentration of GP2 without GM-CSF.

**Abstract Number:** CT227 - Poster Section 51 on April 21, 2026, 9am-12pm

**Abstract Title:** 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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- This abstract and poster will continue to update principal investigators at the conference about the study design of FLAMINGO-01.

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 website [here](#) and [clinicaltrials.gov](https://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](mailto: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](http://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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