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Greenwich LifeSciences Provides Update on Open Label Safety Data from FLAMINGO-01

STAFFORD, Texas, March 17, 2025 (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 announced the following update on FLAMINGO-01 open label safety data.

FLAMINGO-01 Data Safety Monitoring Board (DSMB)

The FLAMINGO-01 DSMB met twice in 2024, most recently in December 2024, and recommended to continue the study as is without modification. No serious adverse events related to GLSI-100 have been reported to date in FLAMINGO-01. Additional safety updates and comparison to the Phase IIb safety data are provided below.

Phase IIb Safety Data

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 compared to 20-50% reduction in recurrence rate by other approved products**
- **Peak immune response at 6 months**
- **No reported serious adverse events attributable to treatment**
- **Well-tolerated safety profile**

Full immunization was received in the Primary Immunization Series (PIS), which included the first 6 GLSI-100 injections over the first 6 months. The PIS elicited a potent immune response as measured by local skin tests and immunological assays. Further, booster injections given every 6 months prolonged the immune response, thereby providing longer-term protection. In the Phase IIb and three Phase I clinical trials, where 146 patients were treated, the GP2 immunotherapy was well tolerated, and there were no reported serious

adverse events related to GLSI-100.

The Phase IIb safety data was published at ASCO in 2021 with the following findings:

- GP2 immunotherapy is well-tolerated and no safety signal for GP2 was identified. Additionally, no serious adverse events related to GP2 immunotherapy were reported over the full 5 year treatment and follow-up periods.
- The majority of patients experienced mild or moderate injection site reactions, which accounted for approximately 70% of reported adverse events.
- The incidence of adverse events was similar across HER2 3+ and HER2 1-2+ breast cancer patients, consistent with the previously reported findings that the immune response was similar across both patient populations. This suggests that GP2 immunotherapy could be a potential treatment in HER2 1-2+ patients or in other HER2 expressing cancers.

FLAMINGO-01 Safety Data

Analysis of the open label data from FLAMINGO-01 has commenced and has been conducted in a manner that maintains the study blind. The open label safety data is based on the patients enrolled to date in FLAMINGO-01 and is thus preliminary. While comparing this preliminary FLAMINGO-01 data to the Phase IIb clinical trial data is possible, these preliminary results from FLAMINGO-01 are not a prediction of future results. It is important to note that this preliminary summary may not reflect results at the end of the study.

A preliminary review of FLAMINGO-01 safety data in both the HLA-A*02 treated and placebo arms and the third open label arm with all other HLA types, shows that GP2 immunotherapy continues to be well-tolerated and that no safety signal for GP2 has yet to be identified across all arms of the study. Like the Phase IIb clinical trial, the most frequent adverse event is injection site reaction, which is also a sign of an immune response. As the study matures, the frequency of events related to GLSI-100 will increase, which based on the current data, suggests that the FLAMINGO-01 safety data is trending towards a similar safety profile to that of the Phase IIb study. As a result, this preliminary analysis, and that of the DSMB, is to recommend no changes to FLAMINGO-01 nor to the investigator brochure, where any new or unexpected safety data might be added.

CEO Snehal Patel commented, "We are pleased that the preliminary safety data from FLAMINGO-01 is consistent with the Phase IIb safety data suggesting that GLSI-100 is well tolerated with no safety signal. The safety data, especially the diameter of injection site reactions, can be measured and thus can be used to assess the magnitude of immune response, along with our GP2 skin test. We look forward to analyzing the immune response data and comparing FLAMINGO-01 preliminary results to the Phase IIb data. There is also the potential that some of the HLA, safety, or immune response data from FLAMINGO-01 will be presented at future scientific conferences as the data continues to mature and patient enrollment continues to accelerate."

About FLAMINGO-01 and GLSI-100

FLAMINGO-01 (NCT05232916) is a Phase III clinical trial designed to evaluate the safety and efficacy of 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 clinical sites from university-based hospitals and cooperative networks with plans to expand into Europe and to open up to 150 sites globally. In the double-blinded arms of the Phase III trial, approximately 500 HLA-A*02 patients will be randomized to GLSI-100 or placebo, and up to 250 patients of other HLA types will 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 Form 10-K for the year ended December 31, 2023 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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