April 2, 2025

Greenwich LifeSciences Announces Positive Immune Response Data from FLAMINGO-01 Phase III Clinical Trial

STAFFORD, Texas, April 02, 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 immune response data.

FLAMINGO-01 Immune Response Data Summary

The Company has analyzed the preliminary immune response data from FLAMINGO-01. Immune response data in both the HLA-A*02 treated and placebo arms and the third open label arm with all other HLA types (non- HLA-A*02), show that GLSI-100 is creating an immune response over time as the frequency of patients exhibiting an injection site reaction or GP2 Delayed-Type Hypersensitivity (DTH) skin test reaction as measured by induration or erythema is increasing with increased vaccinations.

- The number of patients experiencing an immune response increased over time from baseline through the 4th to 6th month vaccinations in **both** HLA-A*02 and non-HLA-A*02 arms.
- In addition, a baseline immune response to GP2 is being observed before any treatment with GP2 in **both** HLA-A*02 and non-HLA-A*02 arms. This result suggests that GP2 is a natural antigen, that may have been part of an immune response in the patient during prior trastuzumab or other treatments.
- These two general immune response findings, immune response at baseline and increasing immune response over time, were also observed in the Phase IIb clinical trial for HLA-A*02 only patients. These results confirm that the HLA prevalence, safety, and immune response in FLAMINGO-01 patients is trending as expected in both HLA arms.
- The Company recently filed patent claims for non-HLA-A*02 patients which may be solely owned by the Company separate from any prior license. These claims are also supported by binding prediction algorithms and in vitro binding experiments conducted by the Company. This represents an invention that was originated by the Company which could double the number of patients eligible for GP2 treatment to approximately 88,000 new patients per year in the US and Europe. The market potential using the drug prices per year of Kadcyla or Enhertu could be in the range of $8-10 billion per year.
- As mentioned in a prior press release, the non-HLA-A02 types that are most commonly

being enrolled in FLAMINGO-01 include HLA-A*03, HLA-A*24, HLA-A*01, HLA-A*11, HLA-A*68, HLA-A*29, HLA-A*30, HLA-A*23, and HLA-A*33.

Analysis of the open label data from FLAMINGO-01 has been conducted in a manner that maintains the study blind. The open label immune response data is based on the patients enrolled to date in FLAMINGO-01 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.

CEO Snehal Patel commented, "We are very encouraged to see that the preliminary results from FLAMINGO-01 show immune responses in both HLA-A*02 and non-HLA-A*02 patients. We are now considering the merits of adding a randomized placebo arm for non-HLA-A*02 patients, transforming this current open label third arm into effectively a second pivotal and blinded Phase III trial. If successful, the Company could pursue approval for both HLA-A*02 and non-HLA-A*02 patients in similar time frames using independent or combined analysis of the two patient groups with the potential to double the market for GP2 to up to $10 billion in revenue per year."

Mr. Patel added, "The Company may choose to expand its immune response analysis of GP2 specific T cells by sequencing the DNA of the T cells at baseline and after treatment with GP2. The T cell sequences can be compared to the immune response increases over time. Expansion into GP2 specific CAR-T cells could potentially become another platform technology to complement GP2 peptide treatment for non-responding higher risk patients. Blood samples have been collected at multiple timepoints for future T cell and immune response analysis."

Previously Published Phase IIb Immune Response 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 immune response data in HLA-A*02 only patients was published at AACR in 2021 with the following findings:

- GP2 immunotherapy generated GP2-specific immune responses leading to promising clinical benefit, thus supporting GP2's mechanism of action.
- Immune responses to GP2 were measured over time using a CD8 T cell dimer binding assay (Dimer Binding Assay) and GP2 DTH skin tests. GP2 immunity peaked at 6 months in HER2 3+ patients after they completed their first 6 immunizations, as measured by the Dimer Binding Assay. The data also shows that for the 2.5 years that the immune response was measured, the immunity was sustained and remained above baseline, resulting in a reduction in metastatic breast cancer recurrences.
- Broad based immune response suggests that GP2 immunotherapy and Herceptin based products may also have the potential to treat low HER2 and other HER2 1-3+ expressing cancers in combination with trastuzumab or trastuzumab antibody drug conjugates.

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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