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

STAFFORD, Texas, Feb. 10, 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 HLA data.

Analysis of the open label data from FLAMINGO-01 has commenced and has been conducted in a manner that maintains the study blind. A preliminary review of FLAMINGO-01 HLA data in both the HLA-A*02 treated and placebo arms and the third open label arm with all other HLA types, shows that approximately 46% of all screened patients have at least one HLA-A*02 allele from either parent.

The main purpose of the open label arm is to investigate the safety and efficacy of GLSI-100 vaccination in patients who do not have an HLA-A*02 allele. It is possible that the open label arm may be large enough to draw immune response and efficacy conclusions. As discussed below, the HLA type can be analyzed by race and ethnicity in those patients who self-reported such information.

CEO Snehal Patel commented, "The review of open label data and the ability to look at multiple patient populations in the Phase III trial will be much greater than was possible in the Phase IIb trial. The HLA-A*02 prevalence of 46% in all screened patients meets our expectations of 40-50% prevalence and supports our sample size estimates for the trial and the interim analysis. We are also interested in studying the 8% of patients who have received HLA-A*02 alleles from both parents, as the mechanism of action in these double HLA-A*02 patients could lead to greater immune response and efficacy."

Mr. Patel further added, "There may be other subgroups of HLA types that can be analyzed in addition to the main arms. Approximately 92% of the patients that are in the HLA-A*02 arms have a second HLA-A type from the other parent that is not HLA-A*02 and could be any of 6 or more other prevalent HLA-A types. We can compare these HLA combinations against each other for immune response and clinical outcome, which could allow for subgroup analysis of HLA-A combinations. The prevalence of various HLA-A types by race or ethnicity may also help to inform the Company in its initial commercial development strategy by suggesting those markets where the most efficacious HLA patient populations may reside."

Background on FLAMINGO-01 Trial Design and HLA Testing

The design of the Phase III trial can be seenhere. The trial is a prospective, randomized, double-blinded, multi-center study. The patient population is defined by major screening criteria and is stratified to balance the patient population between the treated and placebo arms of the trial.

As currently designed, approximately 500 patients with the HLA-A*02 allele will be randomized to receive GLSI-100 (GP2 and GM-CSF) or placebo control in the first two pivotal arms of the trial with a planned interim analysis.

In addition, patients without the HLA-A*02 allele will be enrolled in the third open label arm where all patients will receive GLSI-100 and where all endpoints will be open label. This non-HLA-A*02 arm was recently expanded from 100 to 250 patients based on recommendation of the steering committee and review/approval by the FDA and EMA.

- **HLA-A*02 blinded arms:** A patient has 2 HLA-A genes, one from each parent, thus a single HLA-A*02 patient has received the HLA-A*02 allele from one parent. A double HLA-A*02 patient has received the HLA-A*02 allele from both parents. Both single and double HLA-A*02 patients are enrolled in the HLA-A*02 treated and placebo arms, which are blinded. Those patients who have a single HLA-A*02 allele will also have a second HLA-A gene of any other type.

- **Double HLA-A*02 Potential Mechanism of Action:** Theoretically, a double HLA-A*02 patient may have double the amount of HLA-A*02-GP2 complex presented to the immune system to create cancer killing T-cells during the GLSI-100 vaccinations, and as a cancer cell recurs, the HER2 positive recurring cancer cells may have double the amounts HLA-A*02-GP2 complex for the trained T-cells to target and kill. It may be interesting to investigate immune or clinical response differences between single and double HLA-A*02 patients.

- **Open Label non-HLA-A*02 Third Arm:** If a patient has no HLA-A*02 alleles, they will have 2 different or identical non-HLA-A*02 alleles. These non-HLA-A*02 patients are enrolled in the open label arm, where the immune or clinical response can be assessed as a group or by each HLA-A type, including double HLA-A types, providing the number of patients is sufficiently high to draw conclusions or trends.

- **Additional Information:** A central laboratory in the US is sequencing the DNA of patients to determine both HLA-A allele types. The technology is available to sequence the HLA-B and HLA-C alleles, in addition to the HLA-A allele, to further assess other HLA types that may associate with GP2 to create a positive therapeutic effect. GP2 prediction binding algorithms may suggest that some HLA-B or HLA-C alleles may associate similarly to or stronger than HLA-A*02.

Phase IIb Clinical Trial Results

A variety of HLA types are predicted to associate with GP2 based on binding algorithms, and such binding can be tested in preclinical experiments. However, HLA-A*02 is the most common HLA type, thus it was studied first, and all patients in the Phase IIb trial had at least one HLA-A*02 allele. The HLA data collected did not identify if a patient was double HLA-A*02, nor were any other non-HLA-A*02 alleles identified.

Preliminary Review of FLAMINGO-01 HLA Data

Estimates of HLA prevalence by race are available in literature. As there are many sources and population studies to reference, a general consensus is that HLA-A*02 is prevalent in about 40-50% of the Caucasian population, which is the majority of the population in the US and Europe where the study is being conducted. To assess the prevalence of various HLA-A alleles by race, we have been collecting race and ethnicity data on all patients screened. We have summarized the preliminary data available to date in a blinded manner and have observed the results below. It is important to note that this preliminary summary may not reflect results at the end of the study.

- Across all screened patients, HLA-A*02 prevalence is about 46%. The double HLA-A*02 prevalence, in patients who have received HLA-A*02 alleles from both parents, is about 8%. Because there are 2 HLA-A genes, one from each parent, the total of all prevalence percentages exceeds 100% and is less than 200% because of double HLA-A types. The HLA-A*03, HLA-A*24, and HLA-A*01 prevalences are about 20-25% for each allele. The HLA-A*11, HLA-A*68, HLA-A*29, and HLA-A*30 prevalences are about 9-12% for each allele.

- In those screened patients who self-report as White, at least single or double HLA-A*02 genes are prevalent in approximately 50% of the patients. The double HLA-A*02 alleles are prevalent in 10% of these patients screened. The next most prevalent HLA-A types in the White populations are HLA-A*01 (29%), HLA-A*03 (21%), HLA-A*24 (19%), HLA-A*68 (10%), HLA-A*29 (13%), and HLA-A*11 (9%).

- In those screened patients who self-report as Hispanic or Latino, at least single or double HLA-A*02 alleles are prevalent in approximately 50% of the patients. The double HLA-A*02 genes are prevalent in 7% of these patients screened. The next most prevalent HLA-A types in the Hispanic or Latino populations are HLA-A*01 (20%), HLA-A*24 (22%), HLA-A*68 (22%), HLA-A*30 (18%), HLA-A*29 (13%), and HLA-A*11 (13%).

- In those screened patients who self-report as Black or African-American, at least single or double HLA-A*02 alleles are prevalent in approximately 40% of the patients. The next most prevalent HLA-A types in the Black or African-American populations are HLA-A*68 (33%), HLA-A*03 (27%), HLA-A*30 (27%), HLA-A*24 (13%), HLA-A*29 (13%), and HLA-A*23 (13%).

- In those screened patients who self-report as Asian, at least single or double HLA-A*02 alleles are prevalent in approximately 17% of the patients. The other prevalent HLA-A types are HLA-A*24 (42%), HLA-A*33 (42%), HLA-A*11 (25%), and HLA-A*03 (25%).

The above preliminary Flamingo-01 open label data on HLA-A alleles by race and ethnicity is similar to the data available in literature. If any of the non-HLA-A*02 alleles have a strong association to GP2, it may be interesting to study the immune response and efficacy of GLSI-100 in patients with one allele of that type and one allele that is HLA-A*02 in addition to in patients with the double HLA-A*02 alleles.

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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