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Greenwich LifeSciences Announces Approval to Expand FLAMINGO-01 into the United Kingdom

STAFFORD, Texas, July 22, 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 GLSI-100, an immunotherapy to prevent breast cancer recurrences, today announced the regulatory approval to expand FLAMINGO-01 into the United Kingdom.

The Company's application to expand FLAMINGO-01 into the UK has been formally approved by UK regulators, thus adding potentially 5-10 geographically distributed UK sites to the approximately 170-180 approved sites in the US and Europe.

The Company is collaborating with The Royal Marsden, a leading cancer research institute. Working with The Royal Marsden, we have been in discussions with many academic sites located in the following cities: London (multiple sites), Cambridge, Edinburgh, Oxford, Manchester, Southhampton, Cardiff, and potentially other cities. With regulatory approval, these start-up discussions will now move forward. The principal investigator at Royal Marsden, who will be serving as the UK national principal investigator, also plans to join the Steering Committee.

CEO Snehal Patel commented, "We are very excited to be adding these UK sites from prominent research institutions. The initial introduction was driven by patient interest in the UK. Our hard work with The Royal Marsden in submitting our regulatory application has now paid off with our regulatory approval. The UK population of 70 million is one of the largest populations in Europe and we look forward to offering participation in FLAMINGO-01 to these patients."

The Royal Marsden opened in 1851 as the world's first hospital dedicated to cancer diagnosis, treatment, research and education. Today it operates as a specialist cancer centre. Together with its principal academic partner, The Institute of Cancer Research, London, The Royal Marsden is designated as the UK's only National Institute for Health and Care Research (NIHR) Biomedical Research Centre (BRC) dedicated solely to cancer. The Royal Marsden and The Institute of Cancer Research (ICR) are recognised as one of the top four comprehensive cancer centres in the world for the impact of their research, influencing cancer treatment and care for all cancer patients. As a centre of excellence, they pioneer the very latest in cancer treatments and technologies, as well as leading the way in innovative cancer diagnosis and education.

Based on 2019 and 2021-2022 data from Cancer Research UK, there are approximately 59,400 new breast cancer cases in the UK every year. Breast cancer is the most common

cancer in females, which is 30% of all new female cancer cases.

About FLAMINGO-01 Open Label Phase III Data

More than 1,500 patients have been screened at a screen rate of approximately 600-800 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.
- The non-HLA-A*02 arm 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.

    - The AACR Meeting 2026 delayed-type-hypersensitivity (DTH) poster and the ASCO Meeting 2026 injection site reaction (ISR) poster can be seen and downloaded at the bottom of the Phase III clinical trial tab on the Company's website here.
    - As shown in both posters the frequency of DTH and ISR reactions increased statistically significantly over time.
    - As reported in Table 1 of each poster, each HLA-A type exhibited more frequent immune reactivity after treatment with GLSI-100 than at baseline.
    - 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.

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 posters and results can be summarized as follows and can be seen here:

- 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 170-180 sites globally.

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. In the US and Europe, there are approximately 700,000 new breast cancer patients per year and 9.5 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, 2025, 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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