January 23, 2025

Greenwich LifeSciences Announces Additions of Harvard and Johns Hopkins to Flamingo-01

STAFFORD, Texas, Jan. 23, 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 initiation of new clinical sites in the US.

Both Harvard University and Johns Hopkins University sites were recently added as participating sites in FLAMINGO-01 in the US and both principal investigators, Dr. Laura Spring and Dr. Cesar Santa-Maria have joined the Steering Committee.

The Steering Committee is now 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 –** Professor of Medicine and Winterhof Family Professor of Breast Oncology and Director, Breast Oncology and Clinical Trials Education, University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center

- **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

Dr. Spring is a clinical/translational investigator and breast medical oncologist at the Massachusetts General Hospital Cancer Center (MGH) and Harvard Medical School. She is board certified in internal medicine and medical oncology. Dr. Spring completed residency training at Brigham & Women's Hospital and her medical oncology training through the Dana-Farber/Mass General Brigham Cancer Care Oncology Fellowship Program.

The primary focus of her research is to develop novel therapeutic and biomarker strategies to improve the care of patients with breast cancer. She is particularly interested in blood-based monitoring of localized breast cancer and the use of targeted therapies in the neoadjuvant setting. Dr. Spring is involved with the design and conduct of several breast cancer clinical trials for localized and metastatic breast cancer.

Dr. Spring commented, "We are excited to offer the FLAMINGO-01 trial at MGH for patients with high-risk HER2-positive breast cancer. There is high patient and physician interest in vaccine strategies to reduce recurrence risk."

Dr. Santa-Maria is a board-certified medical oncologist, and Associate Professor of Oncology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, and Director of Breast Clinical Trials in the Breast and Gynecological Malignancies Disease Group. He is a nationally recognized clinical translational researcher in breast immunotherapy, including development of novel vaccines. His work is funded by numerous grants from the NIH, DOD, and several prestigious cancer foundations (ASCO, CCF, BCRF, SGK). He serves on the NCI's Breast Immuno-oncology (BIO) Task Force and the NCCN and holds leadership positions in the ETCTN and TBCRC.

Dr. Santa-Maria commented, "I am thrilled to be opening the FLAMINGO-01 at Johns Hopkins and offering this study for our patients with high-risk HER2-positive breast cancer. A vaccine approach is particularly well suited to this patient population who have completed standard therapy, as risk still remains, and secondary prevention strategies are urgently needed."

Dr. Jaye Thompson, VP Clinical and Regulatory Affairs, commented, "Greenwich is honored to be working with a stellar collection of clinical trial sites around the globe. The institutions, represented by Dr. Spring and Dr. Santa-Maria, exhibit the caliber of sites participating in FLAMINGO-01."

CEO Snehal Patel commented, "Dr. Spring’s interest in biomarkers and targeted therapies,

including HER2 as a target where immune response could be potentially monitored through skin or blood tests, and Dr. Santa-Maria's background and commitment to breast immunotherapy, including novel vaccines, makes for very strong additions to the FLAMINGO-01 Steering Committee. We look forward to collaborating with these new members of the Steering Committee who will help guide us in FLAMINGO-01 and share with us their experiences in enrolling and treating patients in their key geographic locations, while also furthering their research interests."

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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