April 3, 2025

Greenwich LifeSciences Provides Global Update on FLAMINGO-01

STAFFORD, Texas, April 03, 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 provided the following global update on FLAMINGO-01.

Flamingo-01 Progress to Date & Future Plans

The Company recently confirmed that the preliminary HLA prevalence, safety, and immune response data in FLAMINGO-01 patients is trending as expected in both HLA-A*02 and non-HLA-A*02 arms. The non-HLA-A*02 arm was expanded to 250 patients in 2024 with approval from both EU and US regulators. With the new preliminary positive immune response data in these patients, further changes are being considered, including the potential to transform the non-HLA-A*02 open label third arm into effectively a second Phase III trial which could lead to multiple pathways for marketing approval of GLSI-100 and a larger market potential.

In Q1 2025, the Company achieved its highest screening rate of over 150 patients per quarter or the equivalent of 600 patients per year in 40 US sites and 77 EU sites for a total of 117 active sites. In addition, 30 sites in the EU are planned to be activated in 2025 with the potential for another 10 sites to be approved and added in additional EU countries, bringing the total potential sites to over 150 sites globally. Once these sites are activated, the Company is considering a strategy to continue enrolling in both of the HLA-A*02 and non-HLA-A*02 arms until an interim analysis is conducted and the appropriate size of each arm can be further assessed.

US Clinical Sites Participating in Flamingo-01

Approximately 40 US clinical sites with 134 locations, including sites in the US Oncology/Sarah Cannon network, are currently recruiting patients and are listed below and a t www.clinicaltrials.gov/study/NCT05232916. Many of the sites are prominent teaching hospitals, including Yale, Johns Hopkins, Harvard, Huntsman, Moffitt, Stanford, UCSF, UCLA, UCSD, UT Southwestern, UT San Antonio, Columbia, Northwestern, Washington University, Thomas Jefferson, Stony Brook, and Baylor, which is the lead site.

European Clinical Sites and Networks Participating in Flamingo-01

In early 2024, the expansion of Flamingo-01 into 5 EU countries was approved by European regulators. Since that time, 77 clinical trial sites have been activated, and study recruitment is well underway in Spain (29), France (17), Germany (18), Italy (9), and Poland (4).

European academic networks in each country are participating in Flamingo-01 and are listed below. These networks represent the largest oncology focused hospitals and centers in Europe, where breast cancer leaders work in a collaborative manner to help advance promising therapies. The networks hold annual scientific meetings where Flamingo-01 has been introduced and where the Company has presented in the past.

GEICAM is the leading group in breast cancer research in Spain and currently consists of more than 900 experts, who work in more than 200 centers throughout Spain. Since its establishment in 1995, GEICAM has carried out more than one hundred studies in which more than 66,000 women and men have participated.

UCGB or Unicancer is the federation of French comprehensive cancer centers, a major player in cancer research and a network of 20 private, non-profit healthcare centers specialized in oncology, brought together in a health cooperation group.

GBG Forschungs GmbH is one of the world's leading breast cancer research institutes that works together with the academic study group German Breast Group (GBG). With more than 67,000 study participants and 3,500 new patients per year, GBG is the largest breast cancer study group in Germany, consisting of more than 1,000 doctors in over 800 centers.

GIM (Gruppo Italiano Mammella) is a cooperative Italian network for breast cancer research and therapy. GIM brings together over 150 participating centers and around 500 investigators.

Flamingo-01 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

CEO Snehal Patel commented, "Based on the high quarterly screening rate, the current level of interest in the FLAMINGO-01 trial is very high. The Company spent considerable time in Europe this past year training and activating all 77 sites. As these are the largest countries in Europe and the sites are distributed near large population centers, we hope to give as many patients as possible an opportunity to participate in the study. The prestigious sites participating in the study and the prominent KOLs at these sites and on our steering committee have helped to further validate the promise of GLSI-100 and have created momentum that is increasing patient awareness of the Phase IIb results and interest in participating in FLAMINGO-01."

Mr. Patel further added, "With the preliminary analysis of open label data of the Phase III trial complete, we will continue to analyze the open label data, potentially leading to future publications. We will also try to improve the conduct and design of the study with the ultimate goal to reproduce the Phase IIb results, if possible, and to prepare a treatment process that can be easily commercialized. To that end, we are also giving much consideration to the commercial manufacturing, packaging, and distribution of GLSI-100 and have been developing our manufacturing and regulatory strategy for both the US and Europe in parallel to conducting the clinical trial. Our patent strategy includes filing our own patent claims to potentially further extend the patent life of GLSI-100 in addition to the current 12 years of biological exclusivity that GLSI-100 will be eligible for in the US."

List of US Clinical Sites Participating in Flamingo-01 Phase III Clinical Trial

Patients who are interested in participating in the Flamingo-01 Phase III clinical trial can learn more about the study at www.clinicaltrials.gov/study/NCT05232916. Each clinical trial site location is listed on the website under "Contacts and Locations" with a new feature showing each site on a map. Patients should contact a participating clinical trial site near them or Flamingo-01@GreenwichLifeSciences.com for screening. The current listing of US sites from the clinicaltrials.gov website with email contact information for some sites is shown below and will be continually updated during the trial.

Arizona

Arizona Oncology Associates, PC - HOPE
Tucson, Arizona, United States, 85745
Contact: Stacey Kimbell, R.N. Stacey.Kimbell@usoncology.com

Principal Investigator: Aisha Ahmed, MD

California

Providence Medical Foundation
Fullerton, California, United States, 92835
Contact: Rebeca Sanchez 714-446-5177 rebeca.sanchez2@providence.org
Contact: Linda Gozar linda.gozar@stjoe.org
Principal Investigator: Monica Lee, MD

University of California San Diego
La Jolla, California, United States, 92093
Contact: Sauntee Braddock 858-534-8248 sbraddock@health.ucsd.edu
Principal Investigator: Rebecca Shatsky, MD

University of Southern California
Los Angeles, California, United States, 90033

University of California, Los Angeles
Los Angeles, California, United States, 90404
Contact: Monica Rocha MPRocha@mednet.UCLA.edu
Principal Investigator: Aashini Master, DO

Stanford Women's Cancer Center
Palo Alto, California, United States, 74304
Contact: Michelle Le 650-721-4076 michmle@stanford.edu
Principal Investigator: Fauzia Riaz, MD

University of California, San Francisco Helen Diller Family Cancer Center
San Francisco, California, United States, 94158
Contact: Amy Deluca 415-353-7288 amy.deluca@ucsf.edu
Principal Investigator: Laura Huppert, MD

PIH Health Whittier Hospital
Whittier, California, United States, 90602
Contact: Kristine Bradbury Kristine.Bradbury@pihhealth.org
Principal Investigator: Lisa Wang, MD

Colorado

Rocky Mountain Cancer Centers
Denver, Colorado, United States, 80220
Contact: Jennifer Hege Jennifer.Hege@USOncology.com
Principal Investigator: Mabel Mardones, MD

Connecticut

Yale University
New Haven, Connecticut, United States, 06511
Contact: Adam Blanchard adam.blanchard@yale.edu
Principal Investigator: Michael DiGiovanna, MD

District of Columbia

Johns Hopkins Medicine
Washington, District of Columbia, United States, 20016
Contact: Hayden Chae, RN 202-364-7620 hchae5@jhmi.edu
Principal Investigator: Cesar Santa-Maria, MD

Florida
University of Miami
Coral Gables, Florida, United States, 33146
Contact: Maria Ferrer-Guerra mtf89@med.miami.edu
Principal Investigator: Elisa Krill-Jackson, MD
Moffitt Cancer Center
Tampa, Florida, United States, 33612
Contact: Julian Guerrero Julian.Guerrero@Moffitt.org
Principal Investigator: Aixa Soyano Muller, MD

Illinois
Northwestern University
Chicago, Illinois, United States, 60611
Contact: clinicaltrials@northwestern.edu
Principal Investigator: William Gradishar, MD

Maryland
Maryland Oncology Hematology
Annapolis, Maryland, United States, 21401
Contact: Gloria Seho-Ahiable Gloria.Seho-Ahiable@USOncology.com
Principal Investigator: Jeanine Werner, MD

Massachusetts
Massachusetts General Hospital
Boston, Massachusetts, United States, 02114
Contact: MGH Cancer Center New Patient Access Team 877-394-5128
Principal Investigator: Laura Spring, MD

Minnesota
Minnesota Oncology
Maple Grove, Minnesota, United States, 55369
Contact: Kayla McDonald kayla.mcdonald1@usoncology.com
Principal Investigator: Eric Lander, MD

Missouri
Washington University Siteman Cancer Center
Saint Louis, Missouri, United States, 63110
Contact: Tracy Summa 314-362-0263 tracy.summa@wustl.edu
Principal Investigator: Faisal Fa'ak, MD

Nebraska

Nebraska Cancer Specialists
Omaha, Nebraska, United States, 68114
Contact: Heather Cordes hcordes@nebraskacancer.com
Principal Investigator: Mary Heurter Wells, MD

University of Nebraska Medical Center
Omaha, Nebraska, United States, 68198
Contact: jairam.krishnamurthy@unmc.edu
Principal Investigator: Jairam Krishnamurthy, MD

Nevada

Comprehensive Cancer Centers of Nevada
Henderson, Nevada, United States, 89052
Contact: Lindsay Kondo lindsay.kondo@usoncology.com
Principal Investigator: Stephani Christensen, MD

New Jersey

Cooper University
Camden, New Jersey, United States, 08103
Contact: 855-632-2667 Researchcancer@cooperhealth.edu
Principal Investigator: Ahmed K Abou-Hussein, MD

New York

New York Oncology Hematology
Clifton Park, New York, United States, 12065
Contact: Josephine Faruol josephine.faruol@usoncology.com
Principal Investigator: Karen Tedesco, MD

Columbia University
New York, New York, United States, 10032
Contact: cancerclinicaltrials@CUMC.Columbia.edu
Principal Investigator: Julia McGuinness, MD

Stony Brook University
Stony Brook, New York, United States, 11794
Contact: Pushpa Talanki Pushpa.talanki@stonybrookmedicine.edu
Contact: Jules Cohen jules.cohen@stonybrookmedicine.edu
Principal Investigator: Jules Cohen, MD

Ohio

Oncology Hematology Care
Cincinnati, Ohio, United States, 45211
Contact: Douglas Hart Douglas.Hart@usoncology.com
Principal Investigator: Patrick Ward, MD

Oregon

Compass Oncology
Tigard, Oregon, United States, 97223
Contact: Jennifer Thompson Jennifer.Thompson@usoncology.com
Principal Investigator: Jay Andersen, MD

Pennsylvania

Redeemer Health
Meadowbrook, Pennsylvania, United States, 19046
Contact: Nadine Varney 215-544-5832 nvarney@holyredeemer.com
Principal Investigator: Danny Markabawi, MD

Thomas Jefferson University
Philadelphia, Pennsylvania, United States, 19107
Contact: 215-600-9151 onctrialnow@jefferson.edu
Principal Investigator: Maysa Abu-Khalaf, MD

Texas

Texas Oncology - Austin
Austin, Texas, United States, 78745
Contact: Sara Manning Sara.Manning@usoncology.com
Principal Investigator: Kathryn Hudson, MD

Texas Oncology - Dallas
Dallas, Texas, United States, 75246
Contact: Christine Terraciano Christine.Terraciano@usoncology.com
Principal Investigator: Cynthia Osborne, MD

Texas Oncology - Dallas Presbyterian Hospital
Dallas, Texas, United States, 75231
Contact: Nancy Jones nancy.jones@usoncology.com

Principal Investigator: Kristi McIntyre, MD

The University of Texas Southwestern Medical Center
Dallas, Texas, United States, 75390
Contact: Meredith Carter meredith.carter@utsouthwestern.edu
Principal Investigator: Nisha Unni, MD

Baylor College of Medicine
Houston, Texas, United States, 77057
Contact: Maria Rodriguez maria.rodriguez3@bcm.edu
Principal Investigator: Mothaffar Rimawi, MD

The University of Texas Health Sciences Center at San Antonio
San Antonio, Texas, United States, 78229
Contact: Epp Goodwin 210-450-5798 goodwine@uthscsa.edu
Principal Investigator: Virginia Kaklamani, MD

Texas Oncology - San Antonio
San Antonio, Texas, United States, 78240

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Texas Oncology - Gulf Coast
Sugar Land, Texas, United States, 77479
Contact: Melissa Howell Melissa.Howell@usoncology.com
Principal Investigator: Jorge Darcourt, MD
Texas Oncology - Tyler
Tyler, Texas, United States, 75702
Contact: Shelly Maxfield Shelly.Maxfield@USOncology.com
Principal Investigator: Nanna Sulai, MD

Utah

University of Utah Huntsman Cancer Institute
Salt Lake City, Utah, United States, 84112
Contact: Janna Espinosa janna.espinosa@hci.utah.edu
Principal Investigator: Mei Wei, MD

Virginia

Virginia Cancer Specialists
Fairfax, Virginia, United States, 22031
Contact: Carrie Friedman Carrie.Friedman@USOncology.com
Principal Investigator: Shruti Tiwari, MD

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 the most recent Form 10-K for the year ended December 31 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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