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Greenwich LifeSciences Partners with Unicancer Expanding Flamingo-01 into France

STAFFORD, Texas, Jan. 13, 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 activation of clinical sites in France.

According to the latest data collected by the European Cancer Information System (click here), a total of 66,328 new cases of breast cancer were diagnosed in France in 2022, which is the most common cancer diagnosed in women, representing approximately 33% of all cancers in women. Breast cancer is the leading cause of death from cancer in women in France with 14,739 deaths in 2022.

The Company has partnered with Unicancer and its breast cancer group (UCBG), the largest academic breast cancer research network in France. The FLAMINGO-01 study will be activated in approximately 19 French sites in the UCBG network. These sites were approved by French authorities in Q1 2024, which led to site initiation visits and training of 15 sites in Q2-Q4 of 2024, with the remaining 4 sites scheduled for start-up activities in Q1-Q2 of 2025.

Unicancer is the only hospital network in France entirely dedicated to the fight against cancer and the only national hospital federation dedicated to oncology. It brings together 18 Cancer Centers (CLCC), non-profit private healthcare institutions, spread across 20 hospital sites in France, along with two affiliated member institutions. The CLCCs care for nearly 530,000 patients annually (in short-stay, home hospitalization, and outpatient care). Unicancer is also the leading academic sponsor of clinical trials in oncology on a European scale, with 106 active clinical trials sponsored in 2020 and nearly 7,600 patients enrolled. Unicancer also leads flagship programs that enable the use of real-world data to improve the understanding and evaluation of therapeutic strategies, particularly through the ESME platforms, which gather data from over 76,000 cancer patients. Recognized as a leader in research in France, the Unicancer network enjoys a global reputation, contributing to a third of the internationally significant French publications in oncology (source: bibliometric study/Thomson Reuters).

In total, nearly 700 clinical trials (enrollment or follow-up) were sponsored by the Unicancer network in 2020, with over 14% of CLCC patients participating in clinical trials and more than half of the PHRCs (hospital clinical research programs) dedicated to the CLCCs. The 18 CLCCs and the R&D department of Unicancer are ISO 9001:2015 certified for their clinical research. More information on Unicancer can be found at https://www.unicancer.fr/en/.

UCBG develops clinical trials within its network of more than 100 investigating centers covering the whole of France and all types of institutions (University Hospitals, General Hospitals, Comprehensive Cancer Centers, private institutions) to allow wide access to ongoing studies. The UCBG is an internationally recognized intergroup, labeled by the INCa (national cancer institute), and is the preferred contact for the development of studies on breast cancer in France. The UCBG collaborates with the ARCAGY-GINECO intergroup to further increase its network and consolidate its role as a privileged academic interlocutor in France.

"Major work to improve patient care has been carried out and published by the UCBG. Participation in the FLAMINGO study will allow us to stay at the forefront of clinical research in the domain of vaccination against cancer" said Dr. T. Bachelot, President of the UCBG.

Dr. F.C. Bidard, who serves on the FLAMINGO-01 Steering Committee and is the national Principal Investigator for France for FLAMINGO-01 commented, "Anti-tumor vaccines are becoming more and more attractive in addition to standard treatments. GLSI-100 mechanism of action is orthogonal to that of both chemotherapy and anti-HER2 targeted therapies and holds the promise to improve the outcome of patients at high risk of relapse."

Dr. Bidard is a Medical Oncologist and Head of Breast Cancer Group at Institut Curie in Paris and Professor of Medicine at Versailles University. Dr. Bidard has developed several key trials investigating new biomarkers and new therapeutic approaches in breast cancer. Since 2023, he has also served as the Vice-Chair of UCBG.

Jaye Thompson, VP of Clinical and Regulatory Affairs, added "Collaboration with Unicancer allows the Company the opportunity to offer FLAMINGO-01 to patients in France in an efficient manner, reaching all the large population centers in France. I have attended many of the initiation visits and am very impressed with the interest level and professionalism of these leading cancer institutes in France."

CEO Snehal Patel commented, "When we first met Dr. Bidard, he had some proposals for additional clinical trials for GLSI-100 while we were still planning the start-up of the Phase III trial. This relationship eventually led to a partnership with Unicancer to bring Flamingo-01 to the major hospitals in France. We also invited Dr. Biddard to participate on our Steering Committee and are grateful for his guidance and support over the years."

The 19 Unicancer clinical sites are listed on clinicaltrials.gov with an interactive map and are shown below.

Avignon

Sainte-Catherine - Institut du Cancer Avignon-Provence (ICAP)

Beauvais

Centre Hospitalier Simone Veil de Beauvais

Brest

Clinique Pasteur-Lanroze

Caen

Centre François Baclesse (CLCC)

Clermont-Ferrand

Pôle Santé République - ELSAN

Guilherand-Granges

Hôpital privé Drôme Ardèche

Lyon

Centre Léon Bérard

Nice

Centre Antoine Lacassagne

Osny

Centre Hospitalier Privé Sainte-Marie Osny

Paris

Institut Curie

Pontoise

Hôpital NOVO (Nord-Ouest Val-d'Oise)

Quimper

Centre Hospitalier Intercommunal de Cornouaille Quimper Concarneau (CHIC)

Reims

Institut Godinot (CLCC)

Saint-Cloud

Institut Curie

Saint-Grégoire

Centre Hospitalier Privé Saint-Grégoire

Saint-Priest-en-Jarez

Centre Hospitalier Universitaire de Saint-Étienne

Strasbourg

Institut de cancérologie Strasbourg Europe

Vantoux

Hôpital Robert Schuman

Villejuif

Institut Gustave Roussy

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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