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Greenwich LifeSciences Partners with GEICAM in Spain & Conducts First Site Initiation Visits in Europe

STAFFORD, Texas, March 12, 2024 (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 the first clinical sites in Europe in collaboration with GEICAM in Spain.

The Company has partnered with GEICAM, the largest academic breast cancer research network in Spain, where 38 hospitals have agreed to participate in FLAMINGO-01. These sites were recently approved by Spanish authorities, which led to site initiation visits and training of the first sites this past week.

Founded in 1995, GEICAM is a not-for-profit organization leading academic breast cancer research in Spain. It has conducted more than 140 studies involving more than 67,000 women and men and is comprised of more than 900 experts based in over 200 Spanish hospitals. Its mission is to promote independent clinical, epidemiological, and translational research in oncology, with a multidisciplinary approach and under quality criteria, to improve health outcomes, as well as prevention, medical education, and the dissemination of the knowledge of this disease to patients and general society. More information on GEICAM can be found at https://www.geicam.org/.

According to the latest data collected by the European Cancer Information System (ECIS), a total of 35,105 new cases of breast cancer were diagnosed in Spain in 2022, which is the most common cancer diagnosed in women, representing more than 30% of all cancers in women. Breast cancer is the leading cause of death in women between the ages 35-45 in Spain with 6,836 deaths in 2022.

Professor Miguel Martin, who serves on the FLAMINGO-01 Steering Committee, commented, "The HER2+ tumor subtype represents around 18% of all breast cancer cases and in the past was one of the worst prognosis. Anti-HER2 targeting therapies have significantly reduced the relapse rate in patients with early disease, but there is still room for improvement until we reach zero relapse rate. The vaccine being tested in the FLAMINGO-01 study offers an excellent opportunity to reduce these relapses without increasing the side effects of the treatment."

Dr. Martin is Head of the Clinical Oncology Department at Gregorio Marañón General University Hospital and Professor of Medicine at the Faculty of Medicine of the Complutense University, both in Madrid, Spain. He is also the Chair of GEICAM and one of its founding members. He is well known for his activity in developing new medical strategies and

participating as a Principal Investigator in international and national clinical trials. He has 250 articles in journals and books with a cumulative impact factor of 1042 and h-index of 26.

Dr. Eva Carrasco, Scientific Director and CEO of GEICAM and author of more than 70 peer-reviewed original papers in international scientific journals, commented, "The FLAMINGO-01 study is an example of the importance of alliances between the academic field and the pharmaceutical industry and of international collaboration. All this favors the implementation of studies that incorporate the perspective of clinicians from their conception, which represents a boost to breast cancer research and the development of new drugs for the benefit of patients."

Dr. Luis de la Cruz Merino, the national Principal Investigator (PI) for Spain for FLAMINGO-01 commented, "The FLAMINGO-01 trial includes patients with high-risk HER2+ breast cancer who have completed standard adjuvant treatment and the potential beneficial effect of a vaccine based on the GP2 peptide. This peptide, associated with a response-enhancing adjuvant (GM-CSF), appears to induce a specific antitumor immune response in a subgroup of patients with HER2+ (HLA-A*02) breast cancer. This trial aims to compare its efficacy versus observation, in an adjuvant context. The mechanism of action and therapeutic approach is very innovative, since it introduces the study of anti-HER2 vaccines in breast cancer in the context of a randomized phase 3 trial. The data from previous studies in HER2+ breast cancer are very encouraging, with an adequate safety profile, so there are reasonable expectations of success with this vaccine, although of course it requires timely confirmation through this type of trial."

Dr. Luis de la Cruz Merino is Professor of Medicine, Head of the Clinical Oncology Department at Virgen Macarena University Hospital, Seville, Spain. He specializes in cancer and immunology and is responsible for representing all GEICAM participating PIs from a clinical and immunotherapeutic perspective.

CEO Snehal Patel commented, "GEICAM has been a long-term partner of the Company. Our first protocol for FLAMINGO-01 was developed jointly by members of GEICAM and Baylor College of Medicine. From this relationship, we were able to reach out to the other networks in Europe to connect academic networks across multiple countries. We are truly grateful for the time and commitment from the GEICAM team and look forward to working with them in the coming quarters as we ramp up all 38 sites."

The 38 GEICAM clinical sites will be listed on clinicaltrials.gov with an interactive map and are shown below.

Albacete

Albacete University Hospital Complex

Alicante

Dr. Balmis General University Hospital

Badajoz

University Hospital of Badajoz

Barcelona

Clinic Hospital of Barcelona
Hospital del Mar

Caceres

San Pedro de Alcántara Hospital

Cordoba

Reina Sofia University Hospital

Fuenlabrada (Madrid)

University Hospital of Fuenlabrada

Galdácano

Galdakao-Usansolo Hospital

Granada

San Cecilio Clinical University Hospital

Jaén

University Hospital of Jaén

Jerez de La Frontera

University Hospital of Jerez de la Frontera

La Laguna (Tenerife)

University Hospital of the Canary Islands

Lerida

Arnau de Vilanova University Hospital of Lleida

Madrid

Gregorio Marañón General University Hospital
12 de Octubre University Hospital
Fundación Jiménez Díaz University Hospital
HM Sanchinarro University Hospital
Infanta Leonor University Hospital

Majadahonda (Madrid)

Puerta de Hierro Majadahonda University Hospital

Malaga

Regional University Hospital of Malaga

Manresa (Barcelona)

Althaia, Manresa University Care Network

Murcia

Morales Meseguer University General Hospital

Virgen de la Arrixaca University Clinic Hospital

Palma, Majorca (Balearic Islands)

Son Espases University Hospital

San Juan (Alicante)

San Juan University Hospital of Alicante

San Sebastian

Donostia University Hospital

Sant Cugat del Valles (Barcelona)

General University Hospital of Catalonia - Quirónsalud Group

Santa Cruz De Tenerife

Nuestra Señora de Candelaria University Hospital

Santiago de Compostela

University Clinical Hospital of Santiago

Seville

Virgen del Rocío University Hospital
Virgen Macarena University Hospital

Toledo

University Hospital of Toledo

Valencia

General University Hospital Consortium of Valencia
Valencian Institute of Oncology Foundation
University Clinical Hospital of Valencia
Arnau de Vilanova University Hospital of Valencia

Zaragoza

Miguel Servet University Hospital

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 282,000 new breast cancer patients and 3.8 million breast cancer survivors in 2021. 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, 2022 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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