November 26, 2024

Greenwich LifeSciences Partners with GIM in Italy

STAFFORD, Texas, Nov. 26, 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 its partnership with clinical sites in Italy.

The Company has partnered with "Gruppo Italiano Mammella" (GIM), the largest academic cooperative breast cancer research group in Italy, including over 150 participating centers and approximately 500 investigators, with 28 clinical trials on-going today. GIM conducts independent research in innovative technologies and overall, more than 16,000 patients have been involved in approximately 30 studies conducted by the group so far.

According to the latest data collected by the European Cancer Information System (click here), a total of 58,160 new cases of breast cancer were diagnosed in Italy in 2022, which is the most common cancer diagnosed in women, representing approximately 30% of all cancers in women. Breast cancer is the leading cause of death from cancer in women in Italy with 15,455 deaths in 2022.

Nine of the top enrolling institutions belonging to GIM have agreed to participate in FLAMINGO-01. These sites were approved by Italian authorities, which has led to in-person training and start-up activities with all sites. At the annual national GIM conference in September 2024, updates on the FLAMINGO trial and new research proposals of interest to the entire group were discussed.

Professor Grazia Arpino commented, "The FLAMINGO-01 trial is of great interest to me and to my patients. I originally served on the Data Safety Monitory Board of FLAMINGO-01. As I became more familiar with the potential of GLSI-100, I felt that it was important to give the opportunity to patients in Italy to participate in the trial. I therefore presented the FLAMINGO-01 to my colleagues in GIM, and they also enthusiastically agreed to participate. My institution was the first site in Italy to be activated, and we have already started enrollment and treatment of patients."

Grazia Arpino, Professor in Oncology and head of the Breast Cancer Group at the University of Naples Federico II is an expert in mechanism of resistance to endocrine therapy and anti-HER2 therapies in breast cancer. Her research mainly focuses on the development of novel medical strategies to overcome mechanisms of resistance to current anticancer therapies, with more than 137 published articles and an h-index of 39. She is the Principal Investigator in several national and international clinical trials, she is a member of the scientific committee of GIM, and she serves as the Italian National Principal Investigator for FLAMINGO-01.

Professor Sabino De Placido, head of the GIM group, commented, "In the past, HER2-positive breast cancer had a very bad prognosis. Today, with novel anti-HER2 targeting therapies, the relapse rate in patients with early disease has improved, but there is still room for amelioration, particularly in high-risk patients. The vaccine being tested in the FLAMINGO-01 study offers an excellent, innovative opportunity to reduce these relapses without increasing the side effects of treatment."

CEO Snehal Patel commented, "Italy is the first country where we have personally visited and trained all of the sites participating in FLAMINGO-01. These sites are well located near large cities that will provide convenient access to patients. We are truly grateful for the time and commitment from our Italian colleagues."

“The team of trial sites, clinical investigators, and support personnel in Italy has exceeded our expectations, and we are encouraged that FLAMINGO-01 is off to an excellent start in Italy,” added Jaye Thompson, VP of Clinical and Regulatory Affairs.

Some of the most important Italian breast cancer units are participating in the trial: NCI Pascale of Naples with Professor Michelino De Laurentiis, San Martino Hospital in Genova with Professor Lucia Del Mastro, Maggiore Hospital in Novara with Professor Alessandra Gennari, IOV in Padova with Professor Valentina Guarneri, Saint Orsola Hospital in Bologna with Professor Claudio Zamagni, Humanitas Cancer Centre in Rozzano (MI) with Professor Alberto Zambelli, Maugeri Institute in Pavia with Professor Laura Locati, and Gemelli Foundation with Professor Alessandra Fabi.

The full list of participating centers is shown below and listed on clinicaltrials.gov[here](), where an interactive map can be used by patients to locate a hospital to contact regarding potential participation in the clinical trial.

Bologna

Azienda Ospedaliero Universitaria di Bologna Policlinico di Sant'Orsola IRCCS (Istituto Di Ricerca E Di Cura A Carattere Scientifico)

Genova

Ospedale Policlinico San Martino IRCCS (Istituto Di Ricerca E Di Cura A Carattere Scientifico)

Milan

Humanitas Research Hospital

Naples (2)

Azienda Ospedaliera Universitaria Federico II Di Napoli
Istituto Nazionale Tumori Fondazione Pascale IRCCS (Istituto Di Ricerca E Di Cura A Carattere Scientifico)

Novara

Azienda Ospedaliero Universitaria Maggiore della Carità di Novara

Padova

Istituto Oncologico Veneto

Pavia

Istituti Clinici Scientifici Maugeri Spa Società Benefit IRCCS (Istituto Di Ricerca E Di Cura A Carattere Scientifico)

Rome

Fondazione Policlinico Universitario Agostino Gemelli IRCCS (Istituto Di Ricerca E Di Cura A Carattere Scientifico)

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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