January 14, 2025

Greenwich LifeSciences Announces Partnership with GBG in Germany for Flamingo-01

STAFFORD, Texas, Jan. 14, 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 clinical sites in Germany.

The Company has partnered with GBG (German Breast Group), the largest academic breast cancer research network in Germany, where approximately 38 sites have agreed to participate in FLAMINGO-01. Most of the sites have been approved by German authorities which has led to start-up activity in 2024, and the remaining sites are currently under review.

The GBG Forschungs GmbH, which operates in tandem with the German Breast Group, is renowned as one of the world's leading breast cancer research organizations. 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. In 2023, GBG published 64 research articles with a cumulative impact factor of 1,291, showcasing the high quality, cutting-edge research being conducted. More information on GBG can be found at https://www.gbg.de/en/.

According to the latest data collected by the European Cancer Information System (click here), a total of 75,267 new cases of breast cancer were diagnosed in Germany in 2022, which is the most common cancer diagnosed in women, representing approximately 29% of all cancers in women. Breast cancer is the leading cause of death from cancer in women in Germany with 20,601 deaths in 2022.

Professor Sibylle Loibl, who serves on the FLAMINGO-01 Steering Committee, expressed her excitement about the partnership, stating "We are pleased to collaborate with Greenwich LifeSciences on this important immunotherapy study. With a focus on HER2+ high-risk patients who have not achieved a pathologic complete response (pCR), but also those pCR patients who are having a high-risk of relapse despite achieving a pCR, based on GBG data (von Mackelenbergh 2023), this trial has the potential to further improve our understanding of preventing breast cancer recurrences and improving patient outcomes. We are also very pleased that the first patient from Germany was randomized and treated in October 2024."

Dr. Sibylle Loibl serves as Professor (apl) Goethe University Frankfurt/M, Clinical Consultant Centre for Haematology and Oncology/Bethanien Frankfurt/M, CEO of GBG Forschungs GmbH, and Chair of the German Breast Group. She is one of the founding members of GBG. She is well known for her leadership in developing new treatments and organizing

large international clinical trials. By 2023, she had written over 1000 original articles, reviews and book chapters and reached an audience of over 13,000 followers in the last year.

Dr. Marcus Schmidt, the national Principal Investigator (PI) for Germany for FLAMINGO-01 and Professor of Molecular Oncology at the University Medical Center Mainz, highlighted the significance of the study in advancing cancer immunotherapy: "The FLAMINGO-01 trial presents a unique opportunity to evaluate GLSI-100's efficacy in preventing recurrence among HER2-positive breast cancer patients. This trial could pave the way for new treatment paradigms and further the potential of immunotherapies in breast cancer care."

Jaye Thompson, VP of Clinical and Regulatory Affairs, commented, "Adding FLAMINGO-01 sites in Germany will provide access to the largest number of patients in Europe, and GBG has an excellent reputation of providing high quality data. We are fortunate to have a relationship with GBG and the opportunity to offer FLAMINGO-01 to patients in Germany."

Snehal Patel, CEO of Greenwich LifeSciences, added, "Our collaboration with GBG reflects the strength of our mutual commitment to reducing metastatic breast cancer with the latest scientific advancements. By working with one of the world's leading breast cancer research groups, and with Dr. Loibl's active participation on our Steering Committee, we are confident that this partnership will accelerate progress and bring life-saving innovations to the forefront."

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

Augsburg

Hämatologie-Onkologie im Zentrum MVZ

Bayreuth

Klinikum Bayreuth

Berlin

DBZ Onkologie
Helios Klinikum Berlin-Buch GmbH

Bottrop

Marienhospital Bottrop gGmbH

Bremen

Evangelisches Diakonie-Krankenhaus gGmbH

Chemnitz

Klinikum Chemnitz gGmbH

Dessau

Städtisches Klinikum Dessau

Dortmund

St.-Johannes Hospital Dortmund

Dresden

Universitätsklinikum Carl Gustav Carus Dresden

Düsseldorf

MVZ Medical Center Düsseldorf

Eggenfelden

Studienzentrale für das MVZ Eggenfelden e.K.

Essen

Kliniken Essen-Mitte

Frankfurt

Klinikum Frankfurt Höchst

Freiburg

Praxis für interdisziplinäre Onkologie & Hämatologie

Gifhorn

Helios Klinikum Gifhorn

Göttingen

Universitätsmedizin Göttingen

Halle

Krankenhaus St. Elisabeth und St. Barbara Halle (Saale)

Hamburg-Harburg

Gynäkologische Praxisklinik Hamburg Harburg

Hamburg

Mammazentrum Hamburg

Heidelberg

National Center for Tumor Diseases (NCT) Heidelberg

Kassel

Elisabeth-Krankenhaus Kassel

Krefeld

MVZ GynKrefeld GmbH

Langen

Gemeinschaftspraxis für Hämatologie und Onkologie

Leer

MVM Medizinische Verwaltungs- und Managementgesellschaft

Ludwigsburg

RKH Kliniken Ludwigsburg-Bietigheim

Mainz

Universitätsmedizin der Johannes Gutenberg Universität Mainz KöR

Mannheim

Universität Heidelberg

Munich

Klinikum rechts der Isar der TU Muenchen AoeR
München Klinik

Rostock

Klinikum Südstadt Rostock

Rüsselsheim

Gesundheits- und Pflegezentrum Rüsselsheim

Speyer

Diakonissen-Stiftungs-Krankenhaus Speyer (Brustzentrum)

Trier

Klinikum Mutterhaus der Borromäerinnen

Ulm

Universitätsklinikum Ulm

Witten

Marien Hospital Witten

Worms

Klinikum Worms

Wuppertal

Helios Universitätsklinikum Wuppertal

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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