December 29, 2022

# Greenwich LifeSciences Provides Year End Update

STAFFORD, Texas--(BUSINESS WIRE)-- Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the "Company"), a clinical-stage biopharmaceutical company focused on the development of GLSI-100, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery, today provided the following year end update.

**SABCS Update & New Flamingo-01 Steering Committee**

At the 2022 San Antonio Breast Cancer Symposium (SABCS), the Company met with the Flamingo-01 Steering Committee and met with clinicians from the US and various countries in Europe who are participating or planning to participate in Flamingo-01.

The Steering Committee is comprised of the following members and may be expanded as Flamingo-01 is expanded into Europe:

- 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. 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. Sara A. Hurvitz - Professor of Medicine at the David Geffen School of Medicine at UCLA, Medical Director of the Jonsson Comprehensive Cancer Center Clinical Research Unit, Co-Director of the Santa Monica-UCLA Outpatient Oncology Practices, Director of the Breast Cancer Clinical Trials Program at UCLA, and Chief Medical Officer of TRIO-US
- 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. Rimawi, Chair of the Steering Committee, commented, "We are excited about having initiated this trial. We believe that GP2 carries great potential to improve outcomes for patients with HER2 positive breast cancer. With growing interest and excitement about treatments that boost the immune response to cancer, this trial is as timely as it is innovative, and we look forward to conducting it with the exceptional team of investigators we will be collaborating with in Flamingo-01."

CEO Snehal Patel commented, "We were very encouraged by the meetings held at SABCS with clinicians who are participating in or interested in participating in Flamingo-01. The Company will continue to focus on opening more clinical sites than the 20 sites currently opened in the US, expanding Flamingo-01 into the largest countries in Europe, and enrolling

and treating patients. We encourage potential patients to reach out to the clinical sites directly or to email the Company."

**Clinical Sites Participating in Flamingo-01 Phase III Clinical Trial**

Approximately 20 clinical sites with 63 locations at multiple hospitals and the largest oncology network in the US are currently recruiting patients. The Company has added a new page to its website to provide updates to Flamingo-01 which includes a map of participating clinical sites in the US (view here).

Patients who are interested in participating in the Flamingo-01 Phase III clinical trial can contact the Company by email at:

Flamingo-01@GreenwichLifeSciences.com

Patients can obtain the latest clinical site contact information to contact sites directly on www.clinicaltrials.gov with identifier NCT05232916 (view here, then click on "Contacts and Locations" near the top right corner or near the bottom of the web page). The current listing of US sites from www.clinicaltrials.gov with email contact information for some sites is also shown below and will be continually updated during the trial:

**Alabama**

University of Alabama at Birmingham
Birmingham, Alabama, United States, 35294
Principal Investigator: Erica Stringer-Reasor, MD

**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**

University of Southern California
Los Angeles, California, United States, 90033
Principal Investigator: Danielle Sterrenberg, MD

University of California, Los Angeles
Los Angeles, California, United States, 90404
Principal Investigator: Sara Hurvitz

Torrance Memorial Physicians Network
Torrance, California, United States, 90505
Principal Investigator: David Chan, MD

PIH Hospital - Whittier
Whittier, California, United States, 90602
Principal Investigator: Lisa Wang, MD

**Colorado**

Rocky Mountain Cancer Centers
Denver, Colorado, United States, 80220

Principal Investigator: Mabel Mardones, MD

**Florida**

University of Miami

Coral Gables, Florida, United States, 33146

Principal Investigator: Mauricio Escobar, MD

Orlando Health Cancer Institute

Orlando, Florida, United States, 32806

Principal Investigator: Nikita Shah, MD

Moffitt Cancer Center

Tampa, Florida, United States, 33612

Principal Investigator: Aixa Soyano, MD

**Maryland**

Maryland Oncology Hematology (USOR)

Annapolis, Maryland, United States, 21401

Principal Investigator: Jeanine Werner, MD

**Nebraska**

Nebraska Cancer Specialists (USOR)

Omaha, Nebraska, United States, 68114

Contact: Heather Cordes hcordes@nebraskacancer.com

Principal Investigator: Mary Wells, MD

**Nevada**

Comprehensive Cancer Centers of Nevada

Henderson, Nevada, United States, 89052

Principal Investigator: Stephani Christensen, MD

**New York**

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

Principal Investigator: Jules Cohen, MD

**Oregon**

Compass Oncology (USOR)

Tigard, Oregon, United States, 97223

Contact: Jennifer Thompson Jennifer.Thompson@usoncology.com

Principal Investigator: Jay Andersen, MD

**Texas**

Texas Oncology - Austin

Austin, Texas, United States, 78745

Contact: Sara Manning Sara.Manning@usoncology.com

Principal Investigator: Debra A Patt, MD

Texas Oncology - Dallas (USOR)

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

Baylor College of Medicine
Houston, Texas, United States, 77057
Contact: Mothaffar Rimawi, MD
Principal Investigator: Mothaffar Rimawi, MD

Texas Oncology San Antonio (USOR)
San Antonio, Texas, United States, 78240
Contact: Shannon Syring Shannon.Syring@usoncology.com
Principal Investigator: Emmalind Aponte, MD

Texas Oncology - Tyler (USOR)
Tyler, Texas, United States, 75702
Principal Investigator: Nanna Sulai, MD

**Virginia**

Virginia Cancer Specialists
Fairfax, Virginia, United States, 22031
Principal Investigator: Shruti Tiwari, MD

The Colorado and Alabama sites listed above are not yet recruiting. An additional 10 sites near the following locations may be activated in the future: San Francisco, Boston, Chicago, Philadelphia, Houston, Cincinnati, Albany, Dallas, Omaha, and New Haven. Negotiations are under way to add an additional 60-75 sites in Europe, bringing the total number of potential sites in Flamingo-01 to over 90 sites.

**Flamingo-01 Enrollment & Open Label Data**

Future updates or abstracts/posters may include the patient enrollment status of the trial and potentially open label data results.

Mr. Patel further added, “We look forward to analyzing open label data, which may include injection site reactions, delayed type hypersensitivity testing, and immune response data as they become available by HLA type. The objective, although there is no assurance that any of this will be possible, is to assess how Flamingo-01 is progressing compared to the Phase IIb trial, where no recurrences were observed in the GP2 treated patients as previously reported. Along the way, the treatment of patients of different HLA types and the use of new T cell identification technologies may provide additional insights into GP2’s mechanism of action and market potential, including potential additional intellectual property for the Company.”

**Commercial Manufacturing & New Intellectual Property**

In the fourth quarter of 2022, the Company initiated commercial manufacturing activities, which, if successful, would lead to the completion of the first 3 commercial lots of GP2 active ingredient in 2023 and which in total could be used to prepare approximately 200,000 doses of GP2. These commercial lots would be submitted to the FDA in the US and other regulatory agencies in Europe when a marketing application is filed seeking approval to sell GP2 in these respective locations.

In the fourth quarter of 2022, a new patent application was filed with regards to the use of GP2 in an immune response assay that could be used as a biomarker. Plans are in place to potentially file additional patent applications with regards to the use of GP2 in treating patients and with regards to GP2 manufacturing, pharmacy, or injection processes.

**IR Calendar, Bloomberg Interview, & Updated Corporate Presentation Webcast**

The Company's events over the past 6 months can be seen on the events calendar (view here), which include Jefferies and Wainwright investor conferences, BIO Europe partnering conference, Susan G. Komen® Race for Cure, and an interview of CEO Patel aired on Bloomberg (view here). The corporate presentation has also been updated, and the webcast will be updated shortly (view here).

**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/neu 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. 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 100 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.

**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/*neu* (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/neu 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. In a completed randomized, single-blinded, placebo-controlled, multi-center Phase IIb clinical trial led by MD Anderson Cancer Center, no recurrences were observed in patients treated with GLSI-100 in the HER2/neu 3+ adjuvant setting after median 5 years of follow-up, if the patients were treated, followed, and remained disease free over the first 6 months, which is the time required to reach peak immunity and thus maximum efficacy and protection ($p = 0.0338$). For the 146 patients who

have been treated with GLSI-100 to date over 4 clinical trials, treatment was well tolerated and no serious adverse events were observed related to the immunotherapy. Greenwich LifeSciences is planning to commence a Phase III clinical trial using a similar treatment regime as the Phase IIb clinical trial. 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.

**About GP2 Immunotherapy Immune Response**

As previously reported, GP2 immunotherapy generated GP2-specific immune responses, leading to no metastatic breast cancer recurrence in the HER2/*neu* 3+ population in the Phase IIb clinical trial, thus supporting GP2's mechanism of action. Statistically significant peak immunity was reached after 6 months of GP2 treatment, as measured in both the Dimer Binding Assay and the DTH skin test. HER2/*neu* 3+ population immune response was similar to the HER2/*neu* 1-2+ population immune response, suggesting the potential to treat the HER2/*neu* 1-2+ population (including triple negative breast cancer) with GP2 immunotherapy in combination with trastuzumab (Herceptin) based products and other clinically active agents. The broad based immune response suggests the potential for GP2 to treat other HER2/*neu* 1-3+ expressing cancers. For more information on GP2 immune response and clinical data, please visit the Company's clinical trial tab at https://greenwichlifesciences.com/clinical-trials/.

**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, 2021 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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