February 14, 2024

Greenwich LifeSciences Provides Update on Phase III Clinical Trial, Flamingo-01

STAFFORD, Texas, Feb. 14, 2024 (GLOBE NEWSWIRE) -- 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 update on the Phase III clinical trial, Flamingo-01.

Data Safety Monitoring Board (DSMB)

The Flamingo-01 DSMB met twice in 2023 and recommended to continue the study as is without modification. No serious adverse events related to GLSI-100 have been reported to date.

US Clinical Sites Participating in Flamingo-01

Approximately 30 clinical sites with 87 locations at multiple hospitals and the largest oncology network in the US are currently recruiting patients and are listed below. While the first site was activated in August 2022, the first patient was screened and treated in December 2022. Other sites enrolled their first patients in 2023 with additional sites being activated throughout the year. The Company anticipates adding up to an additional 10 sites in 2024, bringing the total sites in the US to approximately 35-40 sites.

European Clinical Sites and Networks Participating in Flamingo-01

Pending European regulatory approval, which is expected in 2024, contracts are in place to add up to an additional 105-120 sites in Europe including Spain (38), France (21), Germany (32), Italy (9), Poland (6), and potentially additional countries in Europe, bringing the total number of potential sites in Flamingo-01 to approximately 140-160 sites between the US and Europe. With a peak enrollment estimate of approximately 2 - 4 patients per site per year, 150 active sites in Flamingo-01 could see peak enrollment of up to 300-600 patients per year. The logistics to supply GP2 and Leukine labeled in each language, to collect patient samples, and to supply all other clinical supplies have been contracted in Europe and are in the final stages of being implemented.

European academic networks in each country are planning to participate in Flamingo-01 and are listed below. These networks represent the largest oncology focused hospitals and centers in Europe, where breast cancer leaders work in a collaborative manner to help advance promising therapies and they hold annual scientific meetings where Flamingo-01 has been introduced and where the company may present in the future.

GEICAM is the leading group in breast cancer research in Spain and currently consists of

more than 900 experts, who work in more than 200 centers throughout Spain. Since its establishment in 1995, GEICAM has carried out more than one hundred studies in which more than 66,000 women and men have participated.

UCGB or Unicancer is the federation of French comprehensive cancer centers, a major player in cancer research and a network of 20 private, non-profit healthcare centers specialized in oncology, brought together in a health cooperation group.

GBG Forschungs GmbH is one of the world's leading breast cancer research institutes that works together with the academic study group German Breast Group (GBG). 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.

GIM (Gruppo Italiano Mammella) is a cooperative Italian network for breast cancer research and therapy. GIM brings together over 150 participating centers and around 500 investigators.

SABCS Update & Flamingo-01 Steering Committee

At the 2023 San Antonio Breast Cancer Symposium (SABCS) and 2023 ASCO Annual Meeting, the Company met with the Flamingo-01 Steering Committee and 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:

- 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. Francois-Clement Bidard – Professor of Medical Oncology, UVSQ/Paris Saclay University, Head of Breast Cancer Group, Institut Curie, Vice-Chair of the French Breast Cancer research group UCBG (Unicancer)
- 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, Head of Division of Hematology/Oncology at University of Washington, Senior Vice President of the Clinical Research Division at the Fred Hutchinson Cancer Center
- Dr. Sibylle Loibl – Professor (apl) Goethe University Frankfurt/M, Clinical Consultant Centre for Haematology and Oncology/Bethanien Frankfurt/M, CEO of GBG Forschungs GmbH & Chair of the German Breast Group (GBG)
- Dr. Miguel Martin – Professor of Medicine, Head, Medical Oncology Service, Gregorio Marañón General University Hospital, Complutense University, Madrid, Chairman of GEICAM
- 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. Hope S. Rugo – Professor of Medicine and Winterhof Family Professor of Breast

Oncology and Director, Breast Oncology and Clinical Trials Education, University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center

- Dr. Laura M. Spring – Assistant Professor, Medicine, Harvard Medical School, Attending Physician, Medical Oncology, Massachusetts General Hospital

The Steering Committee discussed unpublished data, including new research the Company conducted in 2023, that suggests that GP2 may bind to various HLA types and not just HLA-A*02, in addition to discussing the prior data that supports the third arm of the Phase III trial, where 100 non-HLA-A*02 patients are currently planned to be enrolled. The Steering Committee agreed to expand this third arm to 250 patients. Given the encouraging data and the Steering Committee's guidance, the Company will amend the Flamingo-01 protocol to allow up to 250 patients to enroll in the open-label arm of the study.

Dr. Rimawi, Chair of the Steering Committee, commented, "Among my peers, the level of interest in the Flamingo-01 trial is very high. The new sites in Europe will make significant contributions to the trial in terms of patient enrollment as well as overall conduct of the trial. The expansion of the unblinded non-HLA-A*02 arm is also significant as it reflects the interest among patients and investigators in exploring the activity of GLSI-100 in these patients, which may expand the patient population who could benefit from this exciting vaccine."

Dr. Jaye Thompson, VP Clinical and Regulatory Affairs, commented, "We welcome the new US and European members to the Steering Committee and are honored to be receiving their continued guidance in the development of GP2 and oversight of Flamingo-01. The Company spent considerable time in Europe in 2023 planning and organizing in each country. We have trained the country specific research networks in each country with the assistance of the key opinion leaders of these countries and worked closely as a group as we applied through a central European regulatory process to allow Flamingo-01 to expand into Europe. We expect to be able to expand the third arm to 250 patients in a cost-effective manner as 85-100% of the global sites plan to enroll into the third arm. We have also seen an increase in interest from third parties in India and China, countries with the largest prevalence of breast cancer, who are interested in further developing GP2 for their patient populations."

Planned Interim Analysis

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 the third arm.

For the HLA-A*02 randomized arms, 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.

CEO Snehal Patel commented, "With the addition of the European sites and approximately 150 total sites, peak enrollment rates could be reached by the end of 2024 allowing for a refinement in the interim analysis. Currently, enrollment will likely end before the interim analysis is triggered by 14 events. However, the interim analysis could be modified such that an additional sizing interim analysis is conducted before enrollment ends to reaffirm the size

of the 2 randomized arms. While the hazard ratio of 0.3 assumes that the recurrence rate of the treated arm will be 30% of the recurrence rate in the placebo arm and thus a 70% reduction in recurrence rate, and while the Phase II trial showed even greater reduction in recurrence rate, we are likely to see recurrences in the treated arm of the Phase III trial and have designed the trial accordingly. Using the early Phase III trial data to reaffirm the size of the arms of the Phase III trial may be the best information we could use to reduce risk and improve the chances of success of Flamingo-01."

Mr. Patel further added, "While we may have high expectations for the interim analysis midway through the trial, Roche's successful Herceptin and Kadcyla products reduced recurrences by only 50%, while still requiring that all HER2 positive patients be treated. Thus, we believe a similar clinical outcome for Flamingo-01 could occur and could generate similar returns to stakeholders as did Roche's franchise drugs, which at their peak significantly exceeded $5 billion in revenue per year."

Preparation for Filing of BLA in the US

In addition to the submission of the Phase III clinical data, submitting commercial manufacturing data and study reports on the prior clinical trials will be critical to the filing of a BLA for GLSI-100 and for regulatory filings in other countries.

Commercial Manufacturing: The first 3 commercial lots of GP2 active ingredient were completed and released in 2023, representing an important step towards commercialization. The 3 lots in total could be used to prepare approximately 200,000 doses of GP2. In 2024, the first of 3 commercial lots filling GP2 into vials for commercial sale or for clinical use is planned. Data on these commercial lots will be submitted to the FDA in the US and other regulatory agencies in Europe or elsewhere when a marketing application is filed seeking approval to sell GP2 in these respective markets.

Phase II Clinical Trial Study Report: The Company is preparing a comprehensive study report of the Phase II trial for the FDA prior to the filing of a BLA. This report will include the patients with breast cancer recurrences, the last known date of patients who did not recur (censoring data), the adverse events, immune responses, and other final study report analyses. This report will serve to complement the Phase III data and to provide a drug product dossier that can also be submitted to regulatory agencies in other countries for marketing approval. The use of GM-CSF as an adjuvant in GLSI-100 may also be included in the dossier as GM-CSF is only commercially available in the US at this time.

Mr. Patel commented, "We have experienced significant interest from investors, strategics, analysts, and regulators in the 5 year follow-up data we published and the 3 and 4 year follow-up data independently published by the clinical investigators. The differences between these publications can be best explained by the increased maturity of the data as each year progressed. In all 3 publications, no recurrences or a 100% reduction in recurrence rate, were reported in the sub-population that the Flamingo-01 design has been based on and any differences between the number of patients in the treated or placebo groups has been shown to be immaterial."

The Company did not have responsibility for the conduct of the trial or for the data from the Phase II trial. After the trial had already started, the Company received the rights to the Phase II trial data pursuant to a license agreement with the Henry Jackson Foundation (HJF)

that entitled the Company to all of the GP2 data from the Phase II trial and all prior trials, but did not provide the Company with the ability to participate in the Phase II trial as a regulatory clinical sponsor. The lead clinicians and HJF were responsible for project and site management, medical monitoring, data monitoring of case report forms (CRFs), correspondence with the FDA, and creation, data entry and management of the database. The Company was provided study updates but was not provided an opportunity to participate in any of the above activities or to review the publications of the 3 and 4 year follow-up data by the lead clinicians. Thus, the comprehensive study report will rely on cooperation from HJF and the clinical sites who are responsible for providing the final data accurately to the Company.

The Company is currently comparing the final CRFs and database provided by HJF and has noted the following inconsistencies as the comprehensive study report is being prepared. The lead clinicians reported in an annual report to the FDA and in their publication of 4 year follow-up data a 6th recurrence in the HER2 positive control arm of the study. The Company conservatively chose not to report this 6th recurrence since it was not reported in the data provided by HJF, even though adding this recurrence to the control arm would significantly lower the p-value and improve the evidence of efficacy of GLSI-100. As a result of detailed due diligence, the Company became aware in Q4 of 2023 of a potential recurrence in the HER2 positive treated arm. This patient was not reported as a recurrence in the database, on a CRF that should be used for a recurrence, in reports from the lead clinicians to the FDA, or in the 3 or 4 year follow-up data published by the lead clinicians. Some CRFs report a recurrence, but the critical CRF that confirms a recurrence was not completed or entered into the database provided by HJF. The Company has since initiated an effort to confirm with HJF and the clinicians who treated this patient the status of this patient, and if the final CRFs and database should be modified. It appears that this patient, who had completed treatment with GLSI-100, experienced a local recurrence that responded well to additional treatment and survived without additional evidence of disease or distant metastasis for the duration of study follow-up. Any discrepancies noted to date in the review of the censoring date recorded in the database do not materially change the study results and the median duration of follow-up remains 5 years.

Mr. Patel added, "While a recurrence in the control arm would decrease the p-value and still result in a 100% reduction in the recurrence rate, a recurrence in the treated arm would increase the p-value and would result in an 80% reduction in the recurrence rate. In either case, we believe that the reduction in recurrence rate is clinically meaningful and substantial compared to the approximately 20-50% reduction in recurrences of all other approved breast cancer drugs for this patient population. These findings have not materially affected the power of the Phase III study as the assumptions for that design were selected conservatively."

Additional Clinical Trials Under Consideration

The following trials are under consideration, pending additional funding and resources:

- **Phase IIb trial to add an additional 5 years of follow-up to the prior Phase IIb trial**: If possible, extending the follow-up period of the prior Phase IIb trial to up to 10 years may increase the understanding of the length of protection offered by GP2 and the need for additional boosters after the current booster regimen ends. This data may also shed some insight on how to optimize vaccination, how to vaccinate the 3 million

survivors in the U.S. who are many years removed from adjuvant treatment, and how to vaccinate long term metastatic breast cancer survivors. Such a trial extension would require a new follow-up protocol and the cooperation of clinicians and patients who participated in the prior Phase II trial.

- **Phase II/III trial of all low risk HER2 positive patients not eligible for Flamingo-01** If possible, the Company could leverage the current trial infrastructure in the US and Europe to potentially treat all HER2 positive patients and not just those who are high-risk, which is the current design of Flamingo-01. Some patients in the prior Phase II trial were low-risk, which suggests that GP2 may also work in the low-risk population. This trial would be large and lengthy due to fewer recurrence events, but starting it now would be cost effective given the 150 sites which would have access to these patients.

Mr. Patel further commented, "If successful, vaccinating HER2 positive patients who are long term survivors or are at low risk for recurrence could more than double the patient population being pursued in Flamingo-01. Low HER2 breast cancer patients and HER2 positive patients in other cancers also remain possible patient populations to pursue in the future, especially in combination with checkpoint inhibitors and Herceptin antibody drug conjugates."

New Intellectual Property

In the first quarter of 2023, a new patent application was filed with regards to the use of GLSI-100 to reverse a suppressed immune state and to activate an immune response against HER2 positive cancer cells if they reappear. Plans are in place to potentially file additional patent applications with regards to GP2 manufacturing, pharmacy, or injection processes. The Company is developing an assay that may be applicable to the manufacturing of GP2 and is exploring alternative formulations to minimize the reconstitution process in the pharmacy, both of which may provide additional patent opportunities.

2023 Corporate Events

The Company's events in 2023 are listed below and on the events calendar (viewhere), and for the first time included 3 invitations to present at scientific and clinical conferences, a recognition of the promising GP2 clinical data and the potential of Flamingo-01: Think Tank (a collaborative conference with research and clinical experts in breast cancer), Hawaii Breast (featuring the majority of US KOLs), and the 16th International Symposium on Translational Research in Oncology (featuring European scientific and clinical academia).

- Dec 15, 2023 – *2023 Annual Meeting of Stockholders*
- Dec 5 - 9, 2023 – 2023 *San Antonio Breast Cancer Symposium (SABCS)*
- Nov 6 - 8, 2023 – *BIO-Europe Fall 2023*
- Oct 20 - 22, 2023 – *European Society for Medical Oncology (ESMO) Congress 2023*
- Oct 7, 2023 – *2023 Komen Houston Race for the Cure*
- Sep 27 - 29, 2023 – *16th International Symposium on Translational Research in Oncology*
- Sep 11 - 13, 2023 – *H.C. Wainwright 24th Annual Global Investment Conference*
- Aug 16 - 19, 2023 – *Hawaii Breast 2023*
- Jun 5 - 8, 2023 – *BIO 2023 International Convention*
- Jun 2 - 6, 2023 – *2023 American Society of Clinical Oncology (ASCO) Annual Meeting*

- May 11 - 13, 2023 – *European Society for Medical Oncology (ESMO) Breast Cancer 2023*
- Apr 15 - 19, 2023 – *American Association for Cancer Research (AACR) Annual Meeting 2023*
- Feb 6 - 9, 2023 – *2023 BIO CEO & Investor Conference*
- Jan 9 - 13, 2023 – *Breast Cancer Think Tank Conference*

List of US Clinical Sites Participating in Flamingo-01 Phase III Clinical Trial

Patients who are interested in participating in the Flamingo-01 Phase III clinical trial can learn more about the study at www.clinicaltrials.gov/study/NCT05232916. Each clinical trial site location is listed on the website under "Contacts and Locations" with a new feature showing each site on a map. Patients should contact a participating clinical trial site near them or Flamingo-01@GreenwichLifeSciences.com for screening. The current listing of US sites from the clinicaltrials.gov website with email contact information for some sites is shown below and will be continually updated during the trial. Additional sites are planned to be opened at large hospitals in Boston, Philadelphia, and Baltimore/Washington DC.

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

Comprehensive Blood and Cancer Center
Bakersfield, California, United States, 93309
Principal Investigator: Ravindranath Patel, MD

Providence Medical Foundation
Fullerton, California, United States, 92835
Contact: Rebeca Sanchez 714-446-5177 rebeca.sanchez2@providence.org
Contact: Linda Gozar linda.gozar@stjoe.org
Principal Investigator: Monica Lee, MD

University of Southern California
Los Angeles, California, United States, 90033
Contact: Kimberly Arieli Kimberly.Arieli@med.usc.edu
Principal Investigator: Danielle Sterrenberg, MD

University of California, Los Angeles
Los Angeles, California, United States, 90404
Contact: Monica Rocha MPRocha@mednet.UCLA.edu
Principal Investigator: Aashini Master

Stanford Women's Cancer Center
Palo Alto, California, United States, 74304
Contact: Sasha Madan madan2@stanford.edu
Principal Investigator: Fauzia Riaz, MD

University of California, San Francisco Helen Diller Family Cancer Center
San Francisco, California, United States, 94158
Principal Investigator: Hope Rugo, MD
Torrance Memorial Physicians Network
Torrance, California, United States, 90505
Contact: Jessica Yoshinaga jyoshinaga@mednet.ucla.edu
Principal Investigator: David Chan, MD
PIH Hospital - Whittier
Whittier, California, United States, 90602
Contact: Kristine Bradbury Kristine.Bradbury@pihhealth.org
Principal Investigator: Lisa Wang, MD

Colorado
Rocky Mountain Cancer Centers
Denver, Colorado, United States, 80220
Contact: Jennifer Hege Jennifer.Hege@USOncology.com
Principal Investigator: Mabel Mardones, MD

Connecticut
Yale University
New Haven, Connecticut, United States, 06511
Principal Investigator: Michael DiGiovanna, MD

Florida
University of Miami
Coral Gables, Florida, United States, 33146
Contact: Maria Ferrer-Guerra mtf89@med.miami.edu
Principal Investigator: Mauricio Escobar, MD
Orlando Health Cancer Institute
Orlando, Florida, United States, 32806
Contact: Melinda Porter Janice.Porter@orlandohealth.com
Principal Investigator: Nikita Shah, MD
Moffitt Cancer Center
Tampa, Florida, United States, 33612
Contact: Julian Guerrero Julian.Guerrero@Moffitt.org
Principal Investigator: Aixa Soyano, MD

Illinois
Northwestern University
Chicago, Illinois, United States, 60611
Contact: clinicaltrials@northwestern.edu
Principal Investigator: William Gradishar, MD

Maryland

Maryland Oncology Hematology (USOR)
Annapolis, Maryland, United States, 21401
Contact: Gloria Seho-Ahiable Gloria.Seho-Ahiable@USOncology.com
Principal Investigator: Jeanine Werner, MD

Missouri

Washington University Siteman Cancer Center
Saint Louis, Missouri, United States, 63110
Principal Investigator: Faisal Fa'ak, MD

Nebraska

Nebraska Cancer Specialists (USOR)
Omaha, Nebraska, United States, 68114
Contact: Heather Cordes hcordes@nebraskacancer.com
Principal Investigator: Mary Wells, MD
University of Nebraska Medical Center
Omaha, Nebraska, United States, 68198
Principal Investigator: Jairam Krishnamurthy, MD

Nevada

Comprehensive Cancer Centers of Nevada
Henderson, Nevada, United States, 89052
Contact: Lindsay Kondo lindsay.kondo@usoncology.com
Principal Investigator: Stephani Christensen, MD

New York

New York Oncology
Clifton Park, New York, United States, 12065
Contact: Josephine Faruol josephine.faruol@usoncology.com
Principal Investigator: Karen Tedesco, MD
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
Contact: Pushpa Talanki Pushpa.talanki@stonybrookmedicine.edu
Contact: Jules Cohen jules.cohen@stonybrookmedicine.edu
Principal Investigator: Jules Cohen, MD

Ohio

Oncology Hematology Care Clinical Trials
Cincinnati, Ohio, United States, 45211
Contact: Douglas Hart Douglas.Hart@usoncology.com

Principal Investigator: Patrick Ward, MD

Oregon

Compass Oncology (USOR)
Tigard, Oregon, United States, 97223
Contact: Jennifer Thompson Jennifer.Thompson@usoncology.com
Principal Investigator: Jay Andersen, MD

Pennsylvania

Redeemer Health
Meadowbrook, Pennsylvania, United States, 19046
Contact: Nadine Varney 215-544-5832 nvarney@holyredeemer.com
Principal Investigator: Pallav Mehta, 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

Texas Oncology - Dallas Presbyterian Hospital
Dallas, Texas, United States, 75231
Contact: Nancy Jones nancy.jones@usoncology.com
Principal Investigator: Kristi McIntyre, MD

The University of Texas Southwestern Medical Center
Dallas, Texas, United States, 75390
Principal Investigator: Nisha Unni, MD

Baylor College of Medicine
Houston, Texas, United States, 77057
Contact: Rebecca Hildebrandt Rebecca.Hildebrandt@BCM.edu
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 - Gulf Coast
Sugar Land, Texas, United States, 77479
Contact: Melissa Howell Melissa.Howell@usoncology.com
Principal Investigator: Jorge Darcourt, MD

Texas Oncology - Tyler (USOR)
Tyler, Texas, United States, 75702

Contact: Shelly Maxfield Shelly.Maxfield@USOncology.com
Principal Investigator: Nanna Sulai, MD

Utah

University of Utah Huntsman Cancer Institute
Salt Lake City, Utah, United States, 84112
Principal Investigator: Mei Wei, MD

Virginia

Virginia Cancer Specialists
Fairfax, Virginia, United States, 22031
Contact: Carrie Friedman Carrie.Friedman@USOncology.com
Principal Investigator: Shruti Tiwari, MD

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 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/*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. 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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Greenwich
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