

SELLAS Appoints Steering Committee of Leading Acute Myeloid Leukemia Experts for Its Ongoing Phase 3 REGAL Clinical Trial in AML

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- Steering Committee to Provide Scientific Oversight and Guidance for Pivotal Phase 3 Trial of Galinpepimut-S in Patients with Acute Myeloid Leukemia in Second Remission
- Hagop Kantarjian, MD, Professor and Chair of the Department of Leukemia at The University of Texas - MD Anderson Cancer Center to serve as Committee Chair

NEW YORK, April 16, 2020 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on the development of novel cancer immunotherapies for a broad range of cancer indications, today announced the formation of the Steering Committee for its Phase 3 REGAL clinical trial of galinpepimut-S (GPS) in patients with acute myeloid leukemia (AML) who have achieved complete remission after second-line anti-leukemic therapy (CR2).

"We continue to make important progress toward ensuring that our Phase 3 AML trial is a well-executed pivotal study and are working diligently toward its timely execution despite the COVID-19 pandemic," said Dr. Angelos Stergiou, MD, ScD h.c., SELLAS' President & Chief Executive Officer. "We are pleased that our internal clinical leadership team, which includes individuals with extensive late-stage hematology-oncology development experience, is now supplemented by a Steering Committee with deep and extraordinary international hematology experience."

The Steering Committee will provide scientific oversight and guidance of the practical aspects of the ongoing REGAL study. The Steering Committee will also review the results of the trial as they become available, analyze current

clinical practices to identify AML patients most likely to benefit from entry to the study, design and implement the most efficient continued approaches to conducting the study and make recommendations regarding the monitoring of the clinical study in consultation with the independent data monitoring committee.

Dr. M. Yair Levy, MD, Director of Hematologic Malignancies at the Baylor University Medical Center commented, "Over the past several years, new treatment modalities have improved response rates in AML in the second line (salvage) setting, resulting in an increasing number of patients achieving complete remission (CR2). However, patients who successfully enter CR2 represent a clinical population for which there is an enduring unmet medical need, with a median overall survival of around five months. Currently, REGAL is the only Phase 3 study aiming at remission prolongation through maintenance post-CR2 therapy – other than allogeneic stem cell transplantation – that is actively enrolling patients in this setting."

"The REGAL trial is a rigorously designed study which will provide pivotal data assessing the potential contribution of maintenance therapy with galinpepimut-S, an innovatively engineered and promising WT1-targeting immunotherapeutic, in candidate AML patients in CR2. I look forward to reviewing the clinical and safety data as they become available and to serving as a member of its Steering Committee," concluded Dr. Levy.

The Steering Committee currently consists of three members:

- Dr. Hagop Kantarjian, MD, Professor and Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center, and Principal Investigator at MD Anderson for the multi-center Phase 3 REGAL study and Chair of the REGAL Steering Committee*
- Dr. Javier Pinilla-Ibarz, MD, PhD, Director of Immunotherapy for Malignant Hematology at the H. Lee Moffitt Cancer Center and member of the SELLAS Scientific Advisory Board
- Dr. Moshe Yair Levy, MD, Director of Hematologic Malignancies at the Texas Oncology - Baylor Charles A. Sammons Cancer Center

The Company previously reported initial data from the Phase 2a study of galinpepimut-S in AML patients in CR2 at a median follow-up of 19.3 months, showing median overall survival (OS) in vaccine-treated patients of 16.3 months vs. 5.4 months in a patient cohort contemporaneously treated with best standard therapy ($p = 0.0175$). The final analysis, at a median follow-up of 30.8 months, showed a median OS of 21 months in the GPS-treated patient cohort. A second previous Phase 2 study of galinpepimut-S in AML patients who achieved first complete remission (CR1) also met its primary endpoint with an OS rate at 3 years from first vaccination of 47%.

The REGAL study is an ongoing 1:1 randomized, open-label study comparing GPS monotherapy in the maintenance

setting to investigators' choice best available treatment in AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CR2p), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allogeneic stem-cell transplantation. The primary endpoint is OS from the time of study entry. Secondary endpoints include leukemia-free survival, antigen-specific T-cell immune response dynamics, measurable residual disease by multigene array, and assessments of AML clonal evolution and inflammasome molecular signatures in the tumor microenvironment in bone marrow biopsy samples. The Company anticipates interim analysis for safety and futility in the fourth quarter of 2021.

For further information on enrolling in the REGAL study, please visit: <https://www.clinicaltrials.gov/ct2/show/NCT04229979>.

*Dr. Kantarjian's role on the steering committee is under review by MD Anderson's Conflict of Interest Committee to ensure compliance with institutional policy.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel cancer immunotherapeutics for a broad range of cancer indications. SELLAS' lead product candidate, GPS, is licensed from Memorial Sloan Kettering Cancer Center and targets the WT1 protein, which is present in an array of tumor types. GPS has potential as a monotherapy or in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS' second product candidate, nelipepimut-S (NPS), is a HER2-directed cancer immunotherapy with potential for the treatment of patients with early stage breast cancer with low to intermediate HER2 expression, otherwise known as HER2 1+ or 2+, which includes triple negative breast cancer patients, following standard of care. For more information on SELLAS, please visit www.sellaslifesciences.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are "forward-looking statements," including those relating to future events. In some cases, forward-looking statements can be identified by terminology such as "plan," "expect," "anticipate," "may," "might," "will," "should," "project," "believe," "estimate," "predict," "potential," "intend," or "continue" and other words or terms of similar meaning. These statements include, without limitation, statements related to the Company's plans for clinical development of for GPS, including the timing of clinical results, and the potential for GPS as a drug development candidate. These forward-looking statements are based on current plans, objectives, estimates, expectations and intentions, and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the COVID-19 pandemic and its impact on the

Company's clinical plans and business strategy, immune-oncology product development and clinical success thereof, the uncertainty of regulatory approval, and other risks and uncertainties affecting SELLAS and its development programs as set forth under the caption "Risk Factors" in SELLAS' Annual Report on Form 10-K filed on March 13, 2020 and in its other SEC filings. Other risks and uncertainties of which SELLAS is not currently aware may also affect SELLAS' forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof. SELLAS undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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