

# SELLAS Establishes Independent Data Monitoring Committee of Leading Clinical and Biostatistics Experts for Pivotal Phase 3 REGAL Clinical Trial

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- Independent Data Monitoring Committee (DMC) to Review and Evaluate Patient Safety and Efficacy Data for Pivotal Phase 3 Trial of Galinpepimut-S in Patients with Acute Myeloid Leukemia in Second Remission
- Moshe Talpaz, M.D., Associate Director of Translational Research and Associate Chief of the Division of Hematology/Oncology at the University of Michigan Comprehensive Cancer Center to serve as DMC Chair
- Thomas Fleming, Ph.D., Professor and former biostatistics department chair of the University of Washington, Member of the Fred Hutchinson Cancer Research Center, Special Government Employee for the FDA, and a regular member of FDA Advisory Committees to serve as Lead Biostatistician on DMC

NEW YORK, May 18, 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 Independent Data Monitoring Committee (DMC) for its pivotal 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).

The DMC is comprised of an independent group of medical, scientific and biostatistics experts and is responsible for reviewing and evaluating patient safety and efficacy data for the Company's Phase 3 REGAL clinical trial. The DMC will review study data at regular intervals in order to ensure the safety of all patients enrolled in the study. The Committee will also monitor the quality and overall conduct and ensure the validity, scientific and clinical merits of the study, including each site's compliance with the requirements specified in the study protocol. The DMC is charged with assessing such actions in light of an acceptable benefit/risk profile for GPS and will also make

applicable recommendations regarding the clinical trial to SELLAS.

“Our REGAL clinical trial is the only Phase 3 study focused on remission prolongation through maintenance post-CR2 therapy, a significant and growing unmet medical need. As such, it is critically important to maintain the highest levels of integrity for this pivotal study. With the formation of the DMC, comprised of highly regarded and experienced physicians and biostatisticians who will confer with the respected physicians on the Steering Committee recently announced, we believe that we have brought together world class experts to monitor and guide this critical study which has the potential to extend the life of AML patients in CR2,” said Angelos Stergiou, MD, ScD h.c., President & Chief Executive Officer of SELLAS. “Furthermore, the DMC will be able, at its sole discretion, to directly and independently liaise with the U.S. Food and Drug Administration (FDA) in order to discuss potential early unblinding and discontinuation of the study in case of reliable evidence of safety and clinically significant positive efficacy of GPS. We believe that this further strengthens the integrity and conduct of our REGAL study.”

The Data Monitoring Committee currently consists of four members:

- Moshe Talpaz, M.D., Associate Director of Translational Research and Associate Chief of the Division of Hematology/Oncology at the University of Michigan Comprehensive Cancer Center and Chair of the REGAL Data Monitoring Committee
- Thomas Fleming, Ph.D., Professor and former department chair of the University of Washington Department of Biostatistics, Member of the Fred Hutchinson Cancer Research Center, former Director of the Statistical Center for HIV/AIDS Prevention Trial Network, NIAID, Special Government Employee for the FDA, and for more than 25 years, a regular member of several FDA Advisory Committees
- Miguel-Angel Perales, M.D., Chief, Adult Bone Marrow Transplant Service at Memorial Sloan Kettering Cancer Center (MSKCC)
- Stephane de Botton, M.D., Head of the Hematology Department at the Gustave Roussy Cancer Campus in Paris, France

Dr. Moshe Talpaz, commented, “I look forward to working together with the other esteemed members of the Data Monitoring Committee on SELLAS’ important pivotal Phase 3 REGAL study. While significant progress has been made over the last few years in putting AML patients into a second remission, the survival benefit has not yet improved correspondingly. Because those patients are by definition in a remission, risk and benefit must be very carefully balanced and it is of great scientific interest to me to be a part of that process, as GPS may have the potential to prolong survival, as the Chair of the independent data monitoring committee for the study focused specifically on that patient population.”

“It is a privilege to contribute to safeguarding the interests of study participants and to protecting the integrity of a

trial of such importance in enhancing our understanding about the effects of interventions in AML patients in complete remission,” added Dr. Fleming.

The Company previously reported initial data from the Phase 2a study of GPS 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 GPS 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>.

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 MSKCC 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](http://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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