NEWS RELEASE

SELLAS Life Sciences Reaches Target Enrollment ex-China in Phase 3 REGAL Trial of Galinpepimut-S in Acute Myeloid Leukemia

11/29/2023

Independent Data Monitoring Committee Scheduled to Meet This Quarter

NEW YORK, Nov. 29, 2023 (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 therapies for a broad range of cancer indications, today announced that the target patient enrollment outside of mainland China in the ongoing Phase 3 REGAL trial of galinpepimut-S (GPS) in patients with acute myeloid leukemia (AML) who have achieved complete remission following second-line salvage therapy has been reached.

"Reaching target enrollment ex-mainland China in this important study represents a significant milestone for SELLAS, the GPS development program, and the AML patient community," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "We are extremely grateful to the participating patients and investigators who have helped achieve this critical milestone and we look forward to sharing the interim analysis which we expect to occur by the end of this year or early next year based upon our statistical assumptions. We are also looking forward to the upcoming IDMC meeting later this month. REGAL is the most comprehensive study conducted by a biotech company to date in this orphan disease setting. With a strong scientific rationale and supportive clinical data in previously conducted Phase 1 and Phase 2 studies in the AML maintenance setting, we believe GPS holds significant promise as a potential new treatment for AML patients. Furthermore, the positive outcome from the recently completed FDA Type C meeting and FDA's guidance on the advancement of our CMC plans for a BLA filing, assuming positive results from the REGAL study, further strengthens our overall GPS program."

The Phase 3 open-label REGAL trial was designed with formal input from the United States Food and Drug Administration. Over 100 patients have been enrolled in the United States, Europe and Asia in the study which compares GPS monotherapy in the maintenance setting to investigators' choice of 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 overall survival (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.

Based upon the Company's statistical assumptions, the interim analysis (after 60 events) is expected to occur in late 2023 or early 2024 and the final analysis (after 80 events) is on track to occur by the end of 2024. Because these analyses are event driven, they may occur at a different time than currently expected.

GPS has received Fast Track Designation in the United States and Orphan Drug Designation in both the United States and the European Union for AML.

For more information on the REGAL Phase 3 trial of GPS for the treatment of AML, please visit **ClinicalTrials.gov** and reference Identifier NCT04229979.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics 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 the potential as a monotherapy and combination with other therapies to address a broad spectrum of hematologic malignancies and solid tumor indications. The Company is also developing SLS009 (formerly GFH009), a small molecule, highly selective CDK9 inhibitor, which is licensed from GenFleet Therapeutics (Shanghai), Inc., for all therapeutic and diagnostic uses in the world outside of Greater China. 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 GPS clinical development program, including the timing of data therefrom, regulatory strategy, and the timing of future milestones. 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 with 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 16, 2023 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.

Investor Contact
Bruce Mackle
Managing Director
LifeSci Advisors, LLC
SELLAS@lifesciadvisors.com

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