



NEWS RELEASE

SELLAS Life Sciences Announces Positive Recommendation from the Independent Data Monitoring Committee of the Phase 3 REGAL Trial in Acute Myeloid Leukemia

6/17/2024

- The Independent Data Monitoring Committee (IDMC) Recommends Continuation of Phase 3 REGAL Trial Without Any Modifications -
- No Safety or Futility Concerns Were Raised Based on the Efficacy and Safety Assessment of All REGAL Patients -
- Interim Analysis Anticipated by Q4 2024 -

NEW YORK, June 17, 2024 (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 a positive review of the ongoing Phase 3 REGAL clinical trial of galinpepimut-S (GPS) in acute myeloid leukemia (AML) by the Independent Data Monitoring Committee (IDMC). The IDMC conducted a prespecified risk-benefit assessment of unblinded data from the study and has recommended that the trial continue without modifications. Based on a detailed analysis of all unblinded data, the IDMC projects with a high level of confidence that the interim analysis (60 events) will occur by the fourth quarter of 2024.

"We are encouraged with another positive review and the IDMC's recommendation to continue the Phase 3 REGAL trial in AML without any modifications," said Angelos Stergiou, MD, ScD hc, President and Chief Executive Officer of SELLAS. "The committee's review did not raise any safety or futility concerns, further strengthening our confidence in the potential of GPS as a safe and effective treatment option for AML patients. This is the first time the IDMC has provided guidance regarding the timing of the expected interim analysis, by the fourth quarter of this year, based

on their thorough analysis of the REGAL trial data.”

“As a principal investigator from a high enrolling REGAL study site, I am of course delighted to learn that the interim analysis, a key milestone, is upcoming,” said Panagiotis Tsirigotis, MD, Professor of Medicine at the University of Athens and Chief of Leukemia at Attikon University Hospital. “What makes me equally and perhaps even more excited is that now with the REGAL study enrollment completed and upcoming efficacy read-out, I am looking forward to the potential expansion of GPS into other settings, beyond maintenance of second remissions in patients with AML, as it could function as a treatment modality in patients in first remission as well as post bone marrow transplant.”

REGAL is a Phase 3 open-label registrational clinical trial for GPS in AML patients who have achieved complete remission following second-line salvage therapy (CR2 patients). The primary endpoint is overall survival. The IDMC is an independent group of medical, scientific, and biostatistics experts responsible for reviewing and evaluating patient safety and efficacy data for REGAL, and for monitoring quality and overall conduct to ensure the study's validity, scientific and clinical merits. The IDMC charter provides for periodic reviews of safety, efficacy, and futility in addition to the interim and final analyses.

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' other 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 REGAL study and the timing of future milestones related thereto. 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 28, 2024 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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Source: SELLAS Life Sciences Group, Inc.