



NEWS RELEASE

SELLAS Life Sciences' Independent Data Monitoring Committee Recommends Galinpepimut-S REGAL Trial to Continue as Planned

12/8/2022

NEW YORK, Dec. 08, 2022 (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 Independent Data Monitoring Committee (IDMC) for its Phase 3 REGAL study for galinpepimut-S (GPS) in acute myeloid leukemia (AML) performed its initial prespecified risk-benefit assessment of unblinded data from the study and has recommended that the trial continue without modifications. The charter for the IDMC provides for periodic reviews by the IDMC for safety, efficacy and futility in addition to the interim and final analyses.

The REGAL study 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 (OS). The IDMC is an independent group of medical, scientific and biostatistics experts who are responsible for reviewing and evaluating patient safety and efficacy data for the REGAL trial, and for monitoring the quality and overall conduct to ensure the validity, scientific and clinical merits of the study.

"Following a prespecified review of unblinded data by the IDMC in accordance with its charter, its recommendation to continue the REGAL study as is, and with trial conduct and integrity intact, is outstanding news. As we have previously reported, we have seen, based on a blinded review of the data conducted this fall, that patients live longer than expected which triggered modifications to the statistical analysis plan (SAP), in particular to reduce the number of events for the interim and final analyses, which is very encouraging," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS.

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, galinpepimut-S (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 and combination with other therapies to address a broad spectrum of hematologic malignancies and solid tumor indications. The Company is also developing 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 clinical development of GPS 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, risks and uncertainties associated 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 31, 2022 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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