NEWS RELEASE

SELLAS Life Sciences Announces Update on Phase 3 REGAL Clinical Trial Evaluating Lead Asset, Galinpepimut-S, in Acute Myeloid Leukemia

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– Overall Survival Observed in Pooled Patient Data to Date Leads to Changes in Statistical Analysis Plan: Interim Analysis Now at 60 Events and Final Analysis Now at 80 Events –

– 3D Medicines to Participate in REGAL Clinical Trial, Which Will Trigger Significant Milestone Payments to SELLAS –

NEW YORK, Nov. 14, 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 important updates relating to its ongoing Phase 3 open-label registrational clinical trial (the REGAL study) for galinpepimut-S (GPS) in acute myeloid leukemia (AML) patients who have achieved complete remission following second-line salvage therapy (CR2 patients).

The primary endpoint of the REGAL study is overall survival (OS). The trial was originally designed using certain assumptions regarding OS for both the GPS treatment arm and the control arm receiving best available treatment (BAT) which are reflected in the protocol and statistical analysis plan (SAP) for the study. A review of preliminary data to date, which was pooled (i.e., GPS arm plus control arm) and which remains blinded as to treatment arm, suggests that the median OS in the pooled study population is likely considerably longer, by approximately two-fold, than originally anticipated and upon which the SAP was based. Accordingly, the overall duration of the REGAL study is now expected to be longer than initially predicted.

Following consultation with members of the Independent Data Monitoring Committee for the REGAL study and AML key opinion leaders, as well as the recommendations of the Company's biostatistics experts, SELLAS is

implementing changes to the SAP and protocol for the REGAL study as follows:

- The total targeted enrollment in the study will increase from 116 patients to a range of 125 to no more than 140 patients.
- The targeted number of events (deaths) for the interim analysis will be reduced to 60 from 80 and is currently expected to occur in late 2023 or early 2024.
- The targeted number of events (deaths) for the final analysis will be reduced to 80 from 105 and is currently expected to occur by the end of 2024.
- Statistical significance would be achieved by an estimated hazard ratio (HR) for OS of 0.636, corresponding to an OS of 12.6 months versus eight months for GPS versus BAT, respectively.

The Company has developed these changes using a conservative application of the O'Brien-Fleming statistical theory, which is suitable when regulatory approval is expected to be based predominantly on results from a single clinical trial and when mortality is the primary endpoint. The Company has notified the U.S. Food and Drug Administration of these changes through a filing to the investigational new drug application (IND) for GPS.

Additionally, SELLAS' development and commercialization partner for the Greater China territory, 3D Medicines (3DMed), has agreed to participate in the REGAL trial through the inclusion of approximately 20 patients from the Greater China territory. Such participation by 3DMed is possible due to the increase in the target patient enrollment in the study and will trigger significant milestone payments, which SELLAS expects to receive in the first half of 2023. If the REGAL study meets its primary endpoint for efficacy and the Chinese regulatory authorities determine that the REGAL data is sufficient for approval in China, GPS could potentially reach the market in Greater China much earlier than had been anticipated by SELLAS and 3DMed when the parties entered into the license agreement providing rights to 3DMed, triggering additional regulatory and commercialization milestones and royalties for SELLAS.

"The review of the pooled blinded dataset from the REGAL study shows that the entire trial population has a longer than originally expected OS duration," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "The causative reason for this result remains unknown and could be attributed to many factors, including the potential for, and extent of, increased clinical benefit accorded by the active GPS arm as well as an evolving treatment landscape and potentially better care for the patients receiving BAT. However, without unblinding the study, it is currently impossible to confirm or refute any of the possibilities. Upon examining the pooled blinded dataset, we worked expeditiously with our biostatisticians and other clinical advisors to refine our SAP, taking into account the observed longer OS, which has resulted in a reduction of the number of events needed for the interim and final analyses while maintaining a similar hazard ratio."

"Furthermore, our team has agreed on a path forward with our partner 3DMed to allow for 3DMed to participate in

the REGAL trial and to enroll Chinese patients in a Phase 3 study much earlier than anticipated. This has been made possible by the refinements we are making for the REGAL study. Assuming a statistically significant and clinical beneficial outcome of the REGAL study, as well as agreement by the Chinese regulatory authorities that such data is sufficient for approval in China, GPS may become available to patients in China far earlier than originally thought, which would be a positive outcome for patients in need of better AML therapies," continued Dr. Stergiou.

Phase 3 REGAL Study Update Virtual Investor Event

SELLAS will hold a virtual investor event today, November 14, 2022, at 8:30 a.m. ET at which the Company will discuss these updates. The event will be facilitated by SELLAS management, including the Company's President and CEO, Angelos Stergiou, MD, ScD h.c., and Dragan Cicic, MD, Senior Vice President, Clinical Development, who will be joined by leading cancer researcher, M. Yair Levy, M.D., Director of Hematologic Malignancies Research at the Baylor University Medical Center and member of the REGAL Steering Committee.

To attend the live video webcast, please **register** or email **SELLAS@kcsa.com**.

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 global 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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