



NEWS RELEASE

SELLAS Life Sciences Provides Update on Phase 3 REGAL Clinical Trial for Galinpepimut-S in Acute Myeloid Leukemia

10/12/2023

- Enrollment ex-China Expected to be Completed in November 2023 -

- Enrollment in China Expected to Commence this Quarter -

NEW YORK, Oct. 12, 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 provided an update on its Phase 3 open-label registrational clinical trial (the REGAL study) for galinpepimut-S (GPS) in patients with acute myeloid leukemia (AML) who have achieved complete remission following second-line salvage therapy (CR2 patients).

The Company expects to complete enrollment in the REGAL study, other than the 20-25 patients anticipated to be enrolled in China, in November 2023. The number of patients needed for the pre-specified interim and final analyses have already been enrolled. The interim analysis (after 60 events) is on track 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.

The Company anticipates that 3D Medicines Inc. (3D Medicines), its commercialization partner for GPS in Greater China, will begin enrolling patients in China in the REGAL study in the fourth quarter of 2023 which will trigger two development milestone payments totaling \$13.0 million. The Company and 3D Medicines had previously projected that enrollment in China would commence in the third quarter of 2023, however, unforeseen supply-chain delays in China impacted the projected timeline. 3D Medicines has successfully obtained all regulatory permits, recruited

investigators, and set up an expansive network of 11 treatment centers across China for participation in the REGAL study.

The next meeting of the Independent Data Monitoring Committee for the REGAL study is scheduled for the end of November 2023.

"We are pleased to be so close to achieving this most important milestone – the completion of enrollment in the REGAL study - and, at the same time, it is important to note that we already have a sufficient number of patients enrolled for the pre-specified analyses," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "Furthermore, 3D Medicines' enthusiasm for the REGAL study remains high. We expect the first patient dosing in China to take place this quarter which will trigger the milestone payment, and we are exploring options to potentially expedite the payment. Importantly, adding approximately 25 patients from China could potentially facilitate drug approval in this significant market, assuming positive data, further yielding additional milestone payments and royalties for 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, 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 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.

About 3D Medicines Inc.

3D Medicines Inc. is a commercial-stage biopharmaceutical company with a mission to help people with cancer live longer and better. Envisioning a future when cancer is managed as a chronic disease, 3D Medicines focuses on the development of differentiated next-generation immuno-oncology drugs, helping cancer patients live with prolonged survival time and a better quality of life. 3D Medicines has established a pipeline with both next-generation biological macromolecule and chemotherapeutic small-molecule drugs, as well as a professional team capable of global development, registration and commercialization operation.

For more information, please visit <http://www.3d-medicines.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 and the timing for achievement of 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.

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