

SELLAS Life Sciences Receives Fast Track Designation from FDA for SLS009 for Treatment of Relapsed/Refractory Peripheral T-cell Lymphomas

10/30/2023

- SLS009 Demonstrated Promising Efficacy in Phase 1 Study with 36.4% Clinical Response (ORR) in r/r Peripheral T-cell Lymphomas (PTCL); ORR in r/r PTCL Patients with Standard of Care is 25.8% -

- Fast Track Designation Accelerates SLS009's Path to U.S. FDA Submission for Treatment of r/r PTCL -

NEW YORK, Oct. 30, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to SLS009, its novel and highly selective CDK9 inhibitor, for the treatment of relapsed/refractory (r/r) Peripheral T-cell Lymphomas (PTCL). The Fast Track designation is intended to facilitate the development and review of drugs to treat serious conditions and fill an unmet medical need.

"The FDA's decision to grant SLS009 Fast Track designation signifies an important milestone towards developing a safe and effective treatment for PTCL, a group of aggressive and rare non-Hodgkin lymphomas, and underscores the urgent need for innovative therapies such as SLS009 that can significantly improve the outcome of PTCL patients," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "SLS009 has demonstrated very promising clinical responses in PTCL patients in the recently completed dose-escalation portion of the Phase 1 trial in relapsed/refractory hematological malignancies and with the Fast Track designation we are poised to accelerate its development. We are committed to working closely with the FDA and our partner GenFleet Therapeutics to develop this promising treatment for patients in need."

SLS009 demonstrated favorable safety/tolerability and promising clinical efficacy in the recently completed dose-escalation portion of the Phase 1 trial in r/r hematological malignancies. Complete or partial responses were observed in acute myeloid leukemia and lymphoma patients among which four out of eleven patients with PTCL (36.4%) achieved clinical responses including one in continuous treatment for over 56 weeks. The current standard of care for PTCL, belinostat, approved for r/r PTCL, showed in its pivotal Phase 2 study a 25.8% response rate in a similar patient population to that in the SLS009 Phase 1 clinical trial. An open-label, single-arm Phase 1b/2 trial of SLS009 (known as GFH009 in China) to evaluate safety and efficacy in r/r PTCL, at the recommended phase 2 dose of 100 mg once per week, is ongoing in China and, based on the results, may serve as a registrational study.

This initial PTCL study, which will enroll up to 95 patients, is fully funded by GenFleet Therapeutics (Shanghai) Inc. The Company is also actively pursuing potential Breakthrough Therapy designation from the FDA for SLS009 for the treatment of r/r PTCL and has a scheduled meeting in the fourth quarter of 2023 to discuss with the FDA.

Fast Track is a process designed by the FDA to facilitate and expedite the development of investigational treatments that demonstrate a potential to address unmet medical needs in serious or life-threatening conditions. Programs with Fast Track designation can benefit from early and more frequent interactions with the FDA to discuss the candidate's development plan in addition to a rolling submission of the marketing application. Therapeutic candidates with Fast Track designation may also be eligible for priority review and accelerated approval if supported by clinical data.

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 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 clinical development program and

regulatory pathway for SLS009. 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

Source: SELLAS Life Sciences Group, Inc.