

SELLAS Receives FDA Orphan Drug Designation for SLS009 for Treatment of Acute Myeloid Leukemia

10/10/2023

NEW YORK, Oct. 10, 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 Orphan Drug Designation (ODD) for SLS009, a novel and highly selective CDK9 inhibitor, for the treatment of acute myeloid leukemia (AML).

"We are honored to receive the ODD from the FDA. This designation underscores the potential of SLS009 to address a significant unmet medical need for patients with AML," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "SLS009 is a novel and highly selective CDK9 inhibitor that has already shown a favorable safety profile, strong initial efficacy signals, and evidence of anti-tumor activity. With the support of this ODD, we look forward to accelerating SLS009 clinical development and bringing new hope to those suffering from this devastating disease."

SLS009 is a highly selective CDK9 inhibitor, currently being evaluated in an open-label, single-arm, multi-center Phase 2a study in patients with relapsed or refractory AML. The primary objectives of the trial are to evaluate safety, tolerability, and efficacy at two dose levels of SLS009 (once weekly at 45 mg and at the recommended Phase 2 dose, 60 mg) in combination with azacitidine and venetoclax (aza/ven). Top-line data are expected by the end of this year.

The ODD designation was supported by data from the Phase 1 study of SLS009 which met all key study objectives: anti-tumor activity (cell killing) of up to 77.3% bone marrow blast reduction, durable complete remission (CR) with no minimal residual disease (MRD), desired 24 hours > IC90 peripheral blood concentrations after the first infusion,

with IC90 concentrations resulting in up to 97% cancer cell killed, achievement of desired levels of MCL1 and MYC suppression in peripheral blood with decrease in MCL1 or MYC observed in 97% (66/68) of analyzed patients; and, with regard to safety, no dose limiting toxicities, no higher grade non-hematologic toxicities of any kind and some hematologic toxicities difficult to determine in patients with hematologic cancers but short in duration and reversible.

The FDA's Office of Orphan Products Development grants ODD status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. ODD provides benefits to drug developers designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include assistance in the drug development process, tax credits for qualified clinical costs, exemptions from certain FDA fees and seven years of marketing exclusivity.

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 SLS009 clinical development program, including data therefrom, and regulatory strategy. 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.