NEWS RELEASE

SELLAS Announces Positive Data from Preclinical Studies Indicating ASXL1 Mutations as Predictor of Response to SLS009 in Solid Cancers

2024-11-27

- Preselection Method for Cancers Responding to SLS009: High Efficacy of SLS009 Observed in 67% of ASXL1 Mutated Solid Cancers vs 0% in Non-ASXL1 Mutated Cancers –

- ASXL1 Mutations Predictably Identified in Colorectal Cancer (CRC MSI-H) and Non-Small Cell Lung Cancer (NSCLC) in Addition to Hematologic Malignancies -

- Existing Clinical Data Demonstrating SLS009 Efficacy in ASXL1 mutated AML and Safety Across Multiple Cancer Types Lay Foundation for Targeted SLS009 Clinical Trial in Selected Solid Cancers -

NEW YORK, Nov. 27, 2024 (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 data from preclinical studies identifying ASXL1 mutation as key predictor of SLS009, a highly selective CDK9 inhibitor, response in solid cancers.

Based on elucidated biology of ASXL1 mutations, results from SELLAS’ clinical trials in acute myeloid leukemia (AML), and reports of common occurrence of ASXL1 mutations in some solid cancers, the Company performed experiments and analyses to explore the following:

- The frequency of ASXL1 mutations in certain solid cancers, including colorectal carcinomas (CRC) with high level microsatellite instability (MSI-H) and non-small cell lung cancer (NSCLC)
- Whether ASXL1 mutations in solid cancers may predict as high SLS009 efficacy as the efficacy exhibited in AML where ASXL1 and similar mutations demonstrated high response rates in SELLAS’ clinical trials

SELLAS performed experiments in patient derived cell lines (PDCs) exposing them to SLS009 at various concentrations and determining the inhibitory concentration (IC50) for each cell line. All cell lines were analyzed for presence of ASXL1 mutations and other genetic markers. High efficacy was prespecified as IC50 < 100 nM, significantly lower than the standard threshold definition for an effective compound (IC50 < 1,000 nM). This threshold was chosen based on the observed long-lasting concentrations of SLS009 observed in patients, which were ~400 nM.

Negative controls consisted of untreated cell lines, while active negative control varying concentrations of revumenib (drug used in hematologic malignancies). Positive controls involved cell lines treated with staurosporine at different concentrations (staurosporine is a standard control compound for kinase inhibitors due to its high broad-spectrum potency in inhibiting most protein kinases at sub-micromolar concentrations).

The results were as follows:

- In CRC MSI-H, ASXL1 mutations were observed in 7/12 (58%) of PDCs, aligning with predicted frequency of ~55%
- In NSCLC, ASXL1 mutations occurred in 2/6 (33%) studied cell lines, higher than predicted 2.6%
- Overall, in 18 studied solid cancer cell lines, ASXL1 mutations were recorded in 9 cell lines and no ASXL1 mutations were recorded in 9 cell lines which were designated as control
- In ASXL1 mutated cell lines, high SLS009 efficacy (IC50 <100 nM) was observed in 6/9 (67%) solid cancer cell lines and in non-ASXL1 mutated cancer high SLS009 efficacy was observed in 0/9 (0%) of studied solid cancer cell lines
    - In CRC MSI-H, high efficacy (IC50 <100 nM) was observed in 4/7 (57%) of ASXL1 mutated cell lines and in 0/5 (0%) of non-ASXL1 mutated cell lines
    - In NSCLC, high efficacy (IC50 <100 nM) was observed in 2/2 (100%) of ASXL1 mutated cell lines and in 0/4 (0%) of non-ASXL1 mutated cell lines
- No activity was observed in any of the studied cell lines with revumenib (negative control) at any concentration
- Staurosporine activity was confirmed, but interestingly and importantly, SLS009 outperformed positive control staurosporine in 5/9 cell lines

“These findings are incredibly encouraging and validate our approach to developing a targeted solid tumor therapy. We are excited that our hypotheses were confirmed, marking, to the best of our knowledge, the first study to advance the identification of ASXL1 mutations as a potential biomarker for a drug response in solid cancers,” said

Dr. Dragan Cicic, Senior Vice President, Chief Development Officer at SELLAS. “Our experiments show that SLS009 demonstrates high efficacy with low IC50 values and with 67% of mutated cell lines responding positively, compared to no response in non-mutated cell lines. In addition, SLS009 outperformed positive control in 5 out of 9 cell lines, establishing itself as a highly effective therapeutic candidate. These critical findings are the missing pieces, complementing our existing safety and efficacy data in AML, and positions us strongly with SLS009 in solid cancers.”

SELLAS has filed for provisional patent protection for the use of ASXL1 mutations as predictive diagnostic for selection of cancer patients likely to benefit based on clinical data and biology.

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 the 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) - potentially the first and best-in-class differentiated small molecule CDK9 inhibitor with reduced toxicity and increased potency compared to other CDK9 inhibitors. Data suggests that SLS009 demonstrated a high response rate in AML patients with unfavorable prognostic factors including ASXL1 mutation, commonly associated with poor prognosis in various myeloid diseases. 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 GPS clinical development program, including the REGAL study and the timing of future milestones related thereto. 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 28, 2024 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

Media Contact
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Source: SELLAS Life Sciences Group, Inc.