NEWS RELEASE

SELLAS Life Sciences Provides Update on Late-Stage Immunotherapy Clinical Development Pipeline

1/8/2019

Aligned with FDA on Phase 3 Registration-Enabling Trial for Galinpepimut-S (GPS) in Acute Myeloid Leukemia; Trial Expected to Start in Q2 2019

Enrollment of Phase 1/2 Basket Trial of GPS plus Keytruda® (pembrolizumab) Initiated; Interim Analysis Anticipated in Q4 2019

Constructive Discussions with FDA on Nelipepimut-S (NPS) Development Program in Triple Negative Breast Cancer Ongoing with Expected Outcome in Q1 2019

NEW YORK, Jan. 08, 2019 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapies for a broad range of cancer indications, today provides a corporate update on the Company's clinical development of galinpepimut-S (GPS) and nelipepimut-S (NPS), which are both in late-stage development.

"In 2018, SELLAS achieved significant progress towards our corporate and clinical goals, as we advanced our immunotherapy pipeline and completed our first year as a public company," said Dr. Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "As we look to 2019, we are excited to initiate our pivotal Phase 3 program for GPS in acute myeloid leukemia (AML), and are in active discussions with the U.S. Food and Drug Administration (FDA) regarding the registration-enabling Phase 3 trial and potential consideration for accelerated approval and breakthrough designation for NPS to treat triple negative breast cancer. We also are exploring the potential of GPS in combination with pembrolizumab in additional tumor types in the context of a Phase 1/2 basket clinical study and look forward to continued progress across our broad pipeline in the year ahead."

Galinpepimut-S (GPS)

In November 2018, SELLAS aligned with the FDA on the clinical trial design and biostatistical plan for a Phase 3 registrational study for GPS in acute myeloid leukemia (AML). The planned Phase 3 registrational study will be a 1:1 randomized, open-label study comparing GPS in the maintenance setting to investigators' choice of best available treatment (BAT) in adult AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CR2p), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allogeneic stem-cell transplantation. This study will serve as the basis for a Biologics License Application (BLA) submission, subject to positive results, and SELLAS expects to start the Phase 3 trial in the second quarter of 2019.

The Phase 3 study is expected to enroll approximately 116 patients at approximately 50 clinical sites in the United States and Europe. The primary endpoint is overall survival (OS) and secondary endpoints include leukemia-free survival, antigen-specific T-cell immune response dynamics over time and rates of achievement of measurable residual disease (MRD) negativity. The study will have a planned interim safety and futility analysis after 80 events, expected to occur in the third quarter of 2020. GPS was previously granted Fast Track and Orphan Drug designations by the FDA for the treatment of AML.

In December 2018, SELLAS initiated enrollment of the Phase 1/2 open-label, non-comparative, multicenter, multi-arm study of GPS in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with selected WT1-positive advanced cancers, including both hematologic malignancies and solid tumors. This study, which is being conducted under a Clinical Trial Collaboration and Supply Agreement (CTSA) with Merck (known as MSD outside the United States and Canada), will assess the efficacy and safety of the combination, with exploratory long-term follow-up for overall survival and safety. The study will enroll approximately 90 patients at up to 20 centers in the United States. The initial tumor types to be treated will be acute myelogenous leukemia (AML) (patients unable to attain deeper morphological response than partial on hypomethylating agents and who are not eligible for allogeneic hematopoietic stem cell transplant) and ovarian cancer (second or third line), to be followed by triple negative breast cancer (second line), small cell lung cancer (second line), and colorectal cancer (third or fourth line).

Nelipepimut-S (NPS)

Based on promising Phase 2b data presented in 2018, SELLAS is currently in continuing active discussions with the FDA regarding the optimal development path for NPS in triple negative breast cancer (TNBC).

In the Phase 2b study of trastuzumab (Herceptin®) +/- nelipepimut-S (NPS) in HER2 low-expressing breast cancer

patient cohorts, trastuzumab + NPS demonstrated clinically and statistically significant efficacy in the TNBC cohort, with a p-value of 0.013 and a 75.2% reduction in risk of relapse or death. In October 2018, the Data Safety Monitoring Board (DSMB) unanimously concluded that the final analysis of the Phase 2b study data with a median follow-up of 26 months confirmed that TNBC patients should be the key target population for the development of trastuzumab + NPS in the adjuvant setting in early-stage HER2 1+/2+ breast cancer patients.

A preplanned secondary efficacy analysis across human leukocyte antigen (HLA) allele subgroups from the Phase 2b study confirmed the therapeutic potential of NPS in patients with early-stage TNBC in the adjuvant setting across HLA types A-02, -03, -24 and -26, which cover approximately 80-85% of the North American/European populations and 86-90% of Asian/Pacific basin populations.

Additional positive data from the Phase 2b study showed a clinically meaningful and statistically significant decrease in the number of clinically detectable relapses in the TNBC cohort with the combination of trastuzumab + NPS (7.5%) vs. trastuzumab alone (27.3%) (p=0.004). In addition, four pre-defined subgroups of TNBC patients in the trastuzumab + NPS arm demonstrated an average decrease of 84.2% in relative risk of relapse or death at 24 months (p=0.004-0.014).

In a Type C meeting with the FDA, SELLAS discussed several key points of the clinical and regulatory strategy for NPS in combination with trastuzumab for TNBC, including potential for accelerated approval; a registration-enabling Phase 3 trial design and biostatistical plan; and the potential for breakthrough designation. SELLAS expects a further meeting with the FDA in early 2019 regarding the potential for breakthrough designation as well as an additional meeting in the first quarter of 2019 to reach agreement for a final development program for NPS in TNBC.

An abstract summarizing the comprehensive set of results from the final analysis of the NPS + trastuzumab Phase 2b clinical study has been accepted for an oral presentation at the ASCO-SITC Clinical Immuno-Oncology Symposium in San Francisco, CA, on March 2, 2019 at 10:15 AM.

NPS was previously granted Fast Track designation by the FDA for the adjuvant treatment of patients with early stage breast cancer with low to intermediate HER2 expression following standard of care upfront therapy (surgery plus chemotherapy +/- radiotherapy).

Expected 2019 Clinical Milestones

- Regulatory and development program with FDA for NPS in TNBC patients finalized in Q1 2019.
- Phase 3 registration-enabling study of GPS in AML patients initiated in Q2 2019, with a planned interim analysis expected in Q3 2020.

- Interim analysis of Phase 1/2 basket study of GPS with pembrolizumab in multiple tumor types in Q4 2019.

Herceptin® and Keytruda® are registered trademarks of Genentech, Inc. and Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA., respectively, and are not trademarks of SELLAS. The manufacturers of these brands are not affiliated with and do not endorse SELLAS or its products.

About SELLAS Life Sciences Group, Inc.

SELLAS is a clinical-stage biopharmaceutical company focused on novel cancer immunotherapeutics 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 Wilms Tumor 1 (WT1) protein, which is present in an array of tumor types. GPS has potential as a monotherapy or in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS has a Phase 3 clinical trial planned (pending funding availability) for GPS in acute myeloid leukemia (AML) and is also studying GPS in combination with pembrolizumab in multiple indications. SELLAS has received Orphan Drug designations for GPS from the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA) for AML, malignant pleural mesothelioma (MPM), and multiple myeloma (MM); GPS has also received Fast Track designation for AML, MPM and MM from the FDA. SELLAS' second product candidate, nelipepimut-S (NeuVax™, NPS), is a HER2-directed cancer immunotherapy being investigated for the prevention of the recurrence of breast cancer after standard of care treatment in the adjuvant setting. NPS has received Fast Track status designation by FDA for the treatment of patients with early stage breast cancer with low to intermediate HER2 expression, otherwise known as HER2 1+ or 2+, which includes triple negative breast cancer (TNBC) patients, following standard of care.

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 further development of and regulatory pathway for galinpepimut-S (GPS) for acute myeloid leukemia and in combination with immunotherapy in other indications and nelipepimut-S (NPS), including the timing of clinical results, the potential time to market for GPS and NPS, the potential results from a clinical trial and interactions with the U.S. Food and Drug Administration. 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 immune-oncology product development and clinical success thereof, the uncertainty of regulatory approval, the uncertainty of finding potential partners for product candidate development, and other risks and uncertainties affecting SELLAS and its development programs as set forth under the caption “Risk Factors” in Exhibit 99.1 in its Current Report on Form 8-K filed on July 18, 2018 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 Contacts:
Will O’Connor
Stern Investor Relations, Inc.
212-362-1200
ir@sellaslife.com

David Moser, JD
SELLAS Life Sciences Group
813-864-2571
info@sellaslife.com

Source: SELLAS Life Sciences Group