



NEWS RELEASE

SELLAS Highlights Clinical Development Progress and Expected 2020 Milestones

1/13/2020

- Phase 3 Galinpepimut-S (GPS) Acute Myeloid Leukemia (AML) Study Open for Enrollment and Patient Screening Underway -
- Regulatory Feedback Regarding Nelipepimut-S (NPS) in Triple Negative Breast Cancer Expected within Q1 2020 -
- Company to Present at Biotech Showcase™ on Monday, January 13 at 9:30 a.m. PT -

NEW YORK, Jan. 13, 2020 (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 cancer immunotherapies for a broad range of cancer indications, today highlighted its clinical development progress for galinpepimut-S (GPS) and nelipepimut-S (NPS) and outlined expected milestones for 2020.

"We made significant clinical and corporate advances in 2019 and early this month, most notably in our preparations for our Phase 3 registrational study (REGAL study) for GPS in acute myeloid leukemia in patients who achieved complete remission after second-line anti-leukemic therapy (CR2) which has now commenced with patient screening underway," said Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "We are excited to continue progressing our GPS program in 2020; in addition to the REGAL study, we remain focused on advancing GPS in combination with PD-1 agents, pembrolizumab and nivolumab. We are also expecting guidance from the U.S. Food and Drug Administration (FDA) within this quarter regarding our NPS program in triple negative breast cancer after recent discussions with the agency. We are indeed excited about the progress we made in 2019 and early 2020 both, clinically as well as on the corporate level, and look forward to advancing our pipeline of immunotherapies and creating value for our shareholders."

Dr. Stergiou will present a corporate overview at the Biotech Showcase™ on Monday, January 13, 2020 at 9:30 a.m. PT (12:30 p.m. ET) in San Francisco, CA. A live audio webcast of the presentation will be available under “Events & Presentations” in the Investors section of SELLAS’ website at www.sellaslifesciences.com/investors. A replay of the webcast will be available for up to 30 days on SELLAS’ website following the presentation.

2019 and Early 2020 Highlights

Galinpepimut-S (GPS)

- In January 2020, the Company announced that it commenced the Phase 3 (REGAL) clinical trial of GPS in AML and has begun patient screening. The Company expects that the first patient will be treated in February. The pivotal Phase 3 REGAL study is a 1:1 randomized, open-label study comparing GPS monotherapy in the maintenance setting to investigators’ choice of best available treatment in 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. The study is expected to enroll approximately 116 patients across approximately 50 clinical sites in the United States and Europe. The primary endpoint is overall survival (OS) from the time of study entry. The Phase 2 study in AML CR2 patients, which is the same indication as the Phase 3 REGAL study, showed a 10.9 months median OS benefit (16.3 months vs. 5.4 months in contemporaneously treated patients with best standard therapy; p-value=0.0175).
- In November 2019, SELLAS announced that follow-up data from its Phase 1 clinical trial of GPS in combination with nivolumab to treat Wilms Tumor 1 (WT1) positive patients with ovarian cancer in second- or third-line remission continues to support the development of GPS in combination with PD-1 inhibitors. Topline data from this study at 10 months had been presented at the June 2018 meeting of the American Society of Clinical Oncology. The follow-up data show that three of the 11 patients enrolled in the study have continued to show no signs of disease progression. The mean progression free survival (PFS) for these three patients is 35.4 months from the initiation of salvage chemotherapy or mean PFS of 30.1 months from the first administration of GPS plus nivolumab. Based on this follow-up information, the estimated two-year PFS rate for this study is now 27.3% for the intent-to-treat (ITT) patients (n=11) and approximately 30% for patients who received greater than two doses of GPS and nivolumab (n=10), as compared to a historical 3% to 10% PFS rate for patients receiving only salvage chemotherapy. No new serious adverse events were noted during the longer follow-up period.
- In November 2019, SELLAS hosted its first R&D KOL Symposium with internationally renowned experts on immuno-oncology and myeloid malignancies, including Dr. Hagop M. Kantarjian, MD, Professor and Chair of

the Department of Leukemia at the University of Texas MD Anderson Cancer Center, and global principal investigator of the Phase 3 AML REGAL clinical trial.

- In July 2019, SELLAS announced the dosing of the first patient in its Phase 1/2 open-label study of GPS in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab), in patients with selected WT1-positive advanced cancers, including both solid tumors and hematologic malignancies. The two initial indications being studied in this basket study, with approximately 30 patients in total in these indications, are ovarian cancer (second or third line) and colorectal cancer (third or fourth line). The Phase 1/2 open-label, multicenter, multi-arm study is being conducted under a Clinical Trial Collaboration and Supply Agreement with Merck (known as MSD outside the United States and Canada) to assess the efficacy and safety of the combination of GPS and KEYTRUDA®. The primary endpoints of the study include safety and overall response rate, while secondary endpoints include progression-free survival, overall survival and immune response correlates. The study is expected to enroll approximately 90 patients across all arms at up to 20 centers in the U.S. SELLAS expects an interim analysis from this study in the second half of 2020.
- In April 2019, SELLAS announced an agreement with Memorial Sloan Kettering Cancer Center (MSK) for the conduct of an investigator-sponsored clinical trial (IST) of GPS in combination with Bristol-Myers Squibb's anti-PD-1 therapy, nivolumab, in patients with malignant pleural mesothelioma (MPM). The Phase 1 open-label clinical study will enroll patients with MPM who harbor relapsed or refractory disease after having received frontline standard of care multimodality therapy. SELLAS has been informed by MSK that it expects the first patient to be dosed in this study in January 2020.

Nelipepimut-S (NPS)

- Based on promising Phase 2b data presented in 2018, SELLAS is in continued active discussions with the FDA regarding the optimal development path for NPS in triple negative breast cancer (TNBC). The Company provided supplemental information to the FDA in September 2019 and, after recent discussions with the agency, expects feedback from the FDA within the first quarter of 2020.
- In 2019, SELLAS presented immune response data from the TNBC cohort of the Phase 2b study at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) and presented final results from an efficacy and safety data analysis of the Phase 2b study at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium.
- In August 2019, SELLAS announced the completion of enrollment in a Phase 2 randomized IST of NPS in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) in women with ductal carcinoma in situ (DCIS) of the breast who are HLA-A2+ or A3+ positive, express HER2 at IHC 1+, 2+, or 3+

levels, and are pre- or post-menopausal. Initial data from this trial are expected in the first quarter of 2020.

Expected 2020 Clinical Milestones

- First patient dosed in the Phase 3 registration-enabling study of GPS in AML patients in February 2020.
- First patient dosed in the Phase 1 open-label study of GPS with nivolumab in MPM patients in January 2020.
- Interim analysis of the Phase 1/2 basket study of GPS with pembrolizumab in multiple tumor types in the second half of 2020.
- Guidance from the FDA on the regulatory and development pathway for NPS in TNBC patients in the first quarter of 2020.
- Initial data from Phase 2 trial of NPS in DCIS in the first quarter of 2020.

Corporate

- On January 9, 2020, the Company announced that it had entered into a securities purchase agreement with institutional investors to purchase approximately \$6.5 million of its common shares (or pre-funded warrants to purchase common shares in lieu thereof) in a registered direct offering priced at-the-market under Nasdaq rules and warrants to purchase common shares in a concurrent private placement. The combined purchase price for one common share (or pre-funded warrants to purchase common shares in lieu thereof) and a warrant to purchase 0.5 common shares is \$3.9825.
- In June 2019, SELLAS announced the closing of an underwritten public offering of (i) 527,344 shares of common stock together with common stock warrants to purchase 527,344 shares of common stock and (ii) 1,472,656 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock, together with common warrants to purchase 1,472,656 shares of common stock, for net proceeds of approximately \$13.4 million.

Keytruda® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA., and is not a trademark of SELLAS. The manufacturer of this brand is not affiliated with and does not endorse SELLAS or its products.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical 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' second product candidate, nelipepimut-S (NPS), is a HER2-directed cancer immunotherapy with potential 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 patients, following standard of care.

For more information on SELLAS, please visit www.sellaslife.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 Company’s plans for further development of and regulatory plans for GPS and NPS, including the timing of clinical results, and the timing of the closing of its registered direct offering. 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, 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 22, 2019 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

Investor Relations

SELLAS Life Sciences Group, Inc.

917-438-4353

info@sellaslife.com

Source: SELLAS Life Sciences Group