

# SELLAS Life Sciences Provides Business Update and Reports Third Quarter 2019 Financial Results

11/14/2019

- Phase 3 Registrational Trial of Galinpepimut-S (GPS) in Acute Myeloid Leukemia (AML) on Track to Initiate by Year End -

- Clinically Significant Follow-up Data from Phase 1 Trial Continues to Support the Development of GPS in Combination with a PD-1 Inhibitor in Ovarian Cancer -

- R&D Investor Event/KOL Symposium to be Held Friday, November 15, 2019 -

NEW YORK, Nov. 14, 2019 (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 provided a corporate update and reported financial results for the quarter ended September 30, 2019.

The Company's planned Phase 3 registrational randomized, open-label study comparing GPS in the maintenance setting to investigators' choice of best available treatment 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 (the REGAL study) is on track to initiate by year end.

Further, the Company 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. These

follow-up data now 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.

“Given these promising and clinically significant follow-up data from our GPS in combination with a PD-1 inhibitor Phase 1 clinical trial, we are encouraged with regard to the possible clinical activity of this combination approach and we are looking forward to the initial clinical data from our Phase 1/2 basket study of GPS in combination with KEYTRUDA® (pembrolizumab) in the second half of 2020 in a comparable ovarian cancer patient population,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “We are also excited to initiate our Phase 3 registrational study of GPS in patients with AML by year end. We look forward to continued progress in our clinical programs, and to discussing our GPS program in more detail with key opinion leaders during our R&D Investor Event/KOL Symposium to be held tomorrow, November 15, 2019.”

#### Recent Pipeline Highlights

- Galinpepimut-S (GPS) Program

- SELLAS expects that initial clinical sites for its Phase 3 AML registrational study (the REGAL study) will be activated by the end of 2019. This randomized, open-label study will compare GPS in the maintenance setting to investigators' choice of best available treatment 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. Interim data from this study is expected by the end of 2021. The Company entered into a Master Services Agreement with Worldwide Clinical Trials Limited in August 2019 and in October 2019 entered into a work order for the Phase 3 AML clinical trial.
- In July 2019, the Company announced the dosing of the first patient in its Phase 1/2 open-label, non-comparative, multicenter, multi-arm study of GPS in combination with Merck's anti-PD-1 therapy, 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 are ovarian cancer (second or third line) and colorectal cancer (third or fourth line). The primary endpoints of this study include safety and overall response rate, and secondary endpoints include progression-free survival, overall survival and immune response correlates. Initial clinical data is expected from the study in the second half of 2020.

- Nelipepimut-S (NPS) Program

- In August 2019, SELLAS announced completion of enrollment in a Phase 2 investigator-sponsored trial 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. The Phase 2 trial is sponsored and operated by the National Cancer Institute to study NPS' potential clinical effects in earlier-stage disease. The primary endpoint of the trial is the difference in the frequency of newly induced NPS-cytotoxic T lymphocytes (CTL; CD8+ T-cell) in peripheral blood between the two arms of the study, using a dextramer assay. Initial data from this trial is expected by the end of 2019.
- In September 2019, SELLAS submitted to the U.S. Food and Drug Administration (FDA) a supplemental regulatory package with additional information on the optimal regulatory pathway for NPS in patients with triple negative breast cancer (TNBC).

#### Recent Corporate Highlights

- On November 7, 2019, SELLAS effected a 1-for-50 reverse split. Trading on a post-split basis commenced on November 8, 2019. The Company's stockholders had previously approved a reverse split in the range of 1-for-20 to 1-for-60. The reverse stock split is intended to increase the per share trading price of the Company's common stock to satisfy the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market.
- On October 29, 2019, the Company entered into an Equity Distribution Agreement with Maxim Group LLC, as sales agent, in connection with an "at the market offering" under which the Company from time to time may offer and sell shares of its common stock, having an aggregate offering price of up to \$5,000,000. Shares sold under the Equity Distribution Agreement will be offered and sold pursuant to the Company's previously filed and effective Registration Statement on Form S-3 and a prospectus supplement and accompanying base prospectus that the Company filed with the Securities and Exchange Commission. The Company intends to use the net proceeds from the offering for working capital and other general purposes, including the continued development of its product candidates, including clinical trial activities.

#### R&D Investor Day

The Company will host its first R&D Investor Day in New York, NY tomorrow, November 15, 2019. The agenda includes updates regarding the GPS Phase 3 AML clinical trial and Phase 1/2 basket study in combination with pembrolizumab, and scientific discussions from key opinion leaders in cancer immunotherapeutics, 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.

The event will be accessible via webcast on the SELLAS website at [www.sellaslifesciences.com](http://www.sellaslifesciences.com). For more information, please contact Will O'Connor, at [ir@sellaslife.com](mailto:ir@sellaslife.com) or 212.362.1600.

### Third Quarter 2019 Financial Results

**Cash Position:** As of September 30, 2019, cash and cash equivalents totaled approximately \$9.1 million. Subsequent to the end of the third quarter, the Company has issued and sold approximately \$1.9 million of Common Stock pursuant to the Equity Distribution Agreement.

**R&D Expenses:** Research and development expenses were \$1.8 million for the third quarter of 2019, as compared to \$1.7 million for the third quarter of 2018. The \$0.1 million increase was primarily attributable to a \$0.2 million increase in manufacturing related expenses for GPS and a \$0.1 million increase in clinical trial expenses due to the Company's basket trial of GPS in combination with pembrolizumab and start-up costs for the GPS AML Phase 3 study, partially offset by a \$0.1 million decrease in personnel related expenses due to reduced headcount. Research and development expenses for the nine months ended September 30, 2019 were \$5.0 million, as compared to \$5.1 million for the same period in 2018. The decrease of \$0.1 million was primarily attributable to a \$0.9 million decrease in personnel related expenses resulting from reduced headcount and a \$0.1 million decrease in other research and development expenses, partially offset by a \$0.5 million increase in manufacturing related expense for GPS, a \$0.3 million increase in licensing fees, and a \$0.1 increase in clinical trial expenses for the GPS basket trial and start-up costs for the GPS AML Phase 3 study.

**G&A Expense:** General and administrative expenses were \$2.4 million for the third quarter of 2019, as compared to \$1.3 million for the third quarter of 2018. The \$1.1 million increase was due to a \$1.2 million increase in legal fees and a \$0.1 million increase in public company costs, partially offset by \$0.2 million decrease in personnel related expenses due to reduced headcount. General and administrative expenses for the nine months ended September 30, 2019 were \$7.5 million, as compared to \$10.1 million for the nine months ended September 30, 2018. The \$2.6 million decrease during the period was primarily related to a \$0.6 million decrease in legal fees, a \$0.5 million decrease in personnel related expenses due to reduced headcount, a \$0.5 million decrease in public company costs, a \$0.4 million decrease in accounting and audit fees, a \$0.3 million decrease in outsourced consulting fees and a \$0.3 million decrease in other expenses.

**Net Loss:** Net loss attributable to common stockholders was \$11.5 million for the third quarter of 2019, or a basic and diluted loss per share attributable to common stockholders of \$2.68, as compared to a net loss attributable to common stockholders of \$9.4 million for the third quarter of 2018, or a basic and diluted loss per share attributable to common stockholders of \$26.75. Net loss attributable to common stockholders was \$20.5 million for the nine months ended September 30, 2019, or a basic and diluted loss per share attributable to common stockholders of

\$11.37, as compared to a net loss attributable to common stockholders of \$27.9 million for the nine months ended September 30, 2018, or a basic and diluted loss per share attributable to common stockholders of \$137.43.

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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, GPS, is licensed from Memorial Sloan Kettering Cancer Center and targets the WT1 protein, which is present in an array of tumor types. SELLAS' second product candidate, 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.

For more information on SELLAS, please visit [www.sellaslifesciences.com](http://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 Company's plans for further development of and regulatory plans for GPS and NPS, including the timing of clinical results. 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.

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