



NEWS RELEASE

SELLAS Life Sciences Reports Full Year 2020 Financial Results and Provides Business Update

3/23/2021

Entered into Exclusive License Agreement, with \$7.5 Million Upfront License Fee and Potential to Receive up to an Additional \$194.5 Million, with 3D Medicines for Development and Commercialization of Galinpepimut-S in China; Additional \$1 Million Milestone Triggered in February 2021

Strengthened Balance Sheet with Cash and Cash Equivalents of \$35.3 Million as of Year-End

Phase 3 REGAL Study of Galinpepimut-S in Acute Myeloid Leukemia Patients Underway in United States and Europe; Number of Clinical Sites Increased

Manufactured First of Three Registration Batches of GPS Required for Regulatory Approval Filings

NEW YORK, March 23, 2021 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on developing novel cancer immunotherapies for a broad range of indications, today reported its financial results for the full year ended December 31, 2020 and provided a business update.

"Despite numerous challenges caused by the COVID-19 pandemic, during 2020 SELLAS remained steadfast and focused on its core mission to develop innovative cancer immunotherapies to prolong patients' lives. With this goal driving our efforts, the team successfully signed an exclusive license agreement with 3D Medicines to further develop and commercialize galinpepimut-S (GPS) in Greater China, with potential to receive total payments under the agreement of up to \$202 million, including the \$7.5 million upfront license fee received at the end of 2020. This agreement marks the first step in our commercialization strategy for GPS. We look forward to progressing our GPS clinical program in 2021, including the Phase 3 REGAL study of GPS in acute myeloid leukemia (AML) patients which

is currently underway in the United States and Europe,” said Angelos Stergiou, MD, ScD. h.c., President and Chief Executive Officer of SELLAS.

“The fourth quarter of 2020 brought a strong close to a transformative year for SELLAS. Of significance, we successfully strengthened our balance sheet through a registered direct offering, the exercise of warrants and the upfront licensing fee from our agreement with 3D Medicines, ending the year with cash and cash equivalents of \$35.3 million,” concluded Dr. Stergiou.

Pipeline Updates:

Galinpepimut-S (GPS)

- Following commencement of the Phase 3 REGAL study in AML patients in early 2020, the Company began to initiate clinical sites for the study in the United States and, later in 2020, in Europe. As the global COVID-19 pandemic intensified, the Company observed that clinical site initiations and patient enrollment, in general, were delayed due to prioritization of hospital resources towards the COVID-19 pandemic and as a result of the various lockdowns, quarantines and other restrictions in the United States and Europe. The Company took several steps to mitigate the effect of these delays on the timeline for the REGAL study, including increasing the expected number of clinical sites from 50 to up to approximately 135, increasing the number of countries in which sites were or will be initiated, and allocating additional resources, including additional CROs and internal personnel, to the REGAL study. Based upon the Company's current assumptions, including with respect to the continuing impact of COVID-19, the Company anticipates that the planned interim safety and futility analysis for the REGAL study is likely to occur in the first half of 2022 provided that the assumptions regarding COVID-19, including the duration thereof and the availability and uptake of COVID-19 vaccines, especially in Europe, remain unchanged.
- In late 2020, SELLAS manufactured the first of three registration batches of GPS which will be required for regulatory approval filings assuming positive data from the REGAL study. This additional batch will be used in the GPS clinical programs and for clinical supply required to be provided to 3D Medicines pursuant to the license agreement with 3D Medicines.
- In the second half of 2020, the Company received approval from each of the French and German regulatory authorities to advance the REGAL study in those countries. Approvals from additional European health authorities are expected in early 2021 which will allow the Company to expand AML patient enrollment for the REGAL study in Europe.

- In December 2020, SELLAS announced initial data from two early stage clinical studies of GPS in combination with checkpoint inhibitor therapies. Early data from the Company's Phase 1/2 basket study of GPS in combination with Merck's pembrolizumab in 2nd or 3rd line WT1(+) relapsed or refractory metastatic ovarian cancer patients showed a disease control rate of 87.5% at a median follow-up of 9.4 weeks and 100% progression free survival rate at 6 weeks post-therapy initiation in eight evaluable patients. In the Phase 1 investigator sponsored study of GPS in combination with nivolumab in patients with relapsed/refractory malignant pleural mesothelioma (MPM), early data showed a median progression-free survival rate of at least 10 weeks in three evaluable patients. Any prolongation of progression-free interval greater than 8 weeks in primary refractory MPM would be considered clinically meaningful. Further clinical and immunobiological data from both of these studies are expected in the first half of 2021.
- In December 2020, the Company announced an exclusive license agreement with 3D Medicines Inc., a China-based biopharmaceutical company developing next-generation immuno-oncology drugs, for the development and commercialization of GPS, as well as the Company's next generation heptavalent immunotherapeutic GPS+, across all therapeutic and diagnostic uses in the Greater China territory (mainland China, Hong Kong, Macau and Taiwan). The potential licensing fees and milestone payments to SELLAS under the agreement, including an upfront license fee of \$7.5 million paid in December 2020, but exclusive of potential future royalties, could total \$202 million.
- In February 2021, SELLAS triggered a milestone in the amount of \$1.0 million related to completion of a technology transfer plan under its license agreement with 3D Medicines. The Company expects to receive payment of this milestone by the end of the first quarter of 2021.

Nelipepimut-S (NPS)

- In December 2020, SELLAS announced positive final data with up to 6 months follow-up from an investigator-sponsored Phase 2 randomized trial (the VADIS study) of NPS in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) in women with ductal carcinoma in situ (DCIS) of the breast. Preliminary data previously reported showed that treatment with even a single dose of NPS was capable of newly inducing NPS-specific cytotoxic T-lymphocytes (CTLs) in peripheral blood in DCIS patients. The updated data, based on a 6-month follow-up, demonstrate that CD8+ T-cell responses persist long-term post-NPS treatment, with treated patients retaining and modestly enhancing their antigen-specific immune response. The relative change in NPS-CTL% mean values at 6 months post-vaccination was +1,300+450% for the NPS+GM-CSF group vs. 250+150% in the GM-CSF alone group, which was highly statistically significant in favor of the NPS+GM-CSF group: $p=0.000094$.
- In January 2021, the data safety monitoring board recommended, with respect to the ongoing investigator

sponsored study of NPS plus trastuzumab in high risk HER2 3+ breast cancer patients that, given the small size of the study and in order to preserve the statistical power of the study, the primary analysis of the study be completed upon the completion of three years of follow-up on every patient or until more events are collected. The Company expects the primary analysis in this study to be completed by the end of 2021.

- In February 2021, the subgroup analysis of the cohort of patients with triple negative breast cancer (TNBC) from the Phase 2b investigator-sponsored study of NPS plus trastuzumab in HER2 low-expressing breast cancer patients was published in the peer-reviewed journal Clinical Immunology. As previously reported, the subset analysis identified significant improvement in 36-month disease-free survival between NPS (n=55) and placebo (n=44) in TNBC.

Corporate Highlights During and Subsequent to the Fourth Quarter 2020:

- In December 2020, SELLAS closed a registered direct offering receiving net proceeds of approximately \$15.0 million, after deducting placement agent fees and other estimated offering expenses.
- In December 2020, the Company received a non-dilutive license fee of \$7.5 million from 3D Medicines, Inc. pursuant to the license agreement discussed above.
- Between December 2020 and February 2021, the Company received approximately \$11.5 million in net proceeds from the exercise of outstanding warrants.

Financial Results for the Full Year 2020:

Licensing revenue: Licensing revenue for the year ended December 31, 2020 was \$1.9 million which consists entirely of the recognition of \$1.9 million of revenue from the \$7.5 million upfront license fee received in 2020 from the Company's license agreement with 3D Medicines. The Company did not record any licensing revenue for the year ended December 31, 2019.

R&D Expenses: Research and development expenses for the year ended December 31, 2020 were \$9.3 million, as compared to \$7.3 million for the year ended December 31, 2019. The increase was primarily due to clinical trial expenses incurred in connection with the initiation of the Phase 3 REGAL study in 2020.

G&A Expenses: General and administrative expenses for the year ended December 31, 2020 were \$9.6 million, as compared to \$9.9 million for the year December 31, 2019. The decrease was primarily due to a reduction in legal fees and personnel related expenses partially offset by an increase in insurance premiums due to hardening insurance markets.

Net Loss: Net loss attributable to common stockholders was \$16.8 million for the year ended December 31, 2020, or a basic and diluted loss per share attributable to common stockholders of \$2.11, as compared to a net loss attributable to common stockholders of \$28.0 million for the year ended December 31, 2019, or a basic and diluted loss per share attributable to common stockholders of \$10.92.

Cash Position: As of December 31, 2020, cash and cash equivalents totaled approximately \$35.3 million. The strengthened year-end balance sheet is a result of the proceeds received in December 2020 from a registered direct offering, warrant exercises and the upfront license fee from 3D Medicines.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on developing novel cancer immunotherapeutics for a broad range of 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 both as a monotherapy and in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS' second product candidate, nelipecimut-S (NPS), is a HER2-directed cancer immunotherapy with potential to treat patients with early-stage breast cancer with low to intermediate HER2 expression, otherwise known as HER2 1+ or 2+, which includes TNBC patients, following the 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 clinical development of GPS for various cancer indications, including AML, ovarian cancer and MPM, the potential for regulatory approval and commercialization of GPS, statements related to the clinical development of NPS for breast cancer, including DCIS. 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 the COVID-19 pandemic and its impact on the Company's clinical plans, 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 23, 2021 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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