



NEWS RELEASE

# SELLAS Life Sciences Reports Second Quarter 2021 Financial Results and Provides Business Update

8/12/2021

Reported Promising Updated Clinical Data in Ongoing Clinical Trials of Galinpepimut-5 (GPS) in Combination with PD-1 Inhibitors for Malignant Pleural Mesothelioma (MPM) and WT1+ Advanced Ovarian Cancer

Recently Published Outcomes Data for Acute Myeloid Leukemia (AML) Patients Highlights Continued Unmet Need and Expanded Market Opportunity for GPS

Cash Position of \$29.9 million as of June 30, 2021

To Host Virtual Investor Symposium on GPS on August 17, 2021

NEW YORK, Aug. 12, 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 quarter ended June 30, 2021 and provided a business update.

"We were pleased to report in June updated clinical data for our two earlier stage studies of GPS in combination with PD-1 inhibitors – the combination of GPS with nivolumab (Opdivo®) in MPM patients and GPS with pembrolizumab (Keytruda®) in advanced ovarian cancer patients. We will continue our analyses as we collect more data over the remainder of the year," said Angelos Stergiou, MD, ScD. h.c., President and Chief Executive Officer of SELLAS. "We also activated additional clinical sites and continued to enroll patients in the United States and Europe for our Phase 3 REGAL study of GPS in AML patients, and expect to activate additional sites in the European Union (EU) as well as other countries outside of the EU throughout the remainder of 2021."

"Also, we note recently published data in the journal Bone Marrow Transplantation regarding the outcomes of AML patients, including those who undergo transplant, which clearly shows that there continues to be a large unmet

need in the treatment of AML even among those who successfully receive a transplant but harbor minimal residual disease. In our completed Phase 2 study of AML patients who achieved first remission (CR1), overall survival for patients treated with GPS was 48.5 months from time of enrollment. The retrospective analysis of the pooled outcomes for AML patients who underwent a transplant in the article published in Bone Marrow Transplantation indicates that the median overall survival from the time of transplant is approximately 26 months. Given the results of our studies in AML CR1 patients, we believe that there is strong scientific rationale for consideration of a study in the post-transplantation setting," concluded Dr. Stergiou.

#### Pipeline Updates:

##### Galinpepimut-S (GPS)

- In June 2021, a peer-reviewed article was published in the journal Bone Marrow Transplantation which included a comprehensive retrospective analysis of survival outcomes in 4,280 AML patients treated in more than 450 blood and marrow transplant centers worldwide between 2007 and 2015. The analysis demonstrates the high unmet medical need to extend survival in AML patients. The published analysis shows that even among patients eligible to receive a bone marrow transplant, considered to be the only potential curative therapy in AML, less than half of the patients are alive five years after initial diagnosis. The analysis highlights the importance of the presence of minimal residual disease, or MRD, with patients who harbored MRD at the time of transplant having only 34%-37% probability of surviving five years. In the Company's completed Phase 2 study of AML patients who achieved first remission (CR1), overall survival (OS) for patients treated with GPS was 48.5 months from the time of enrollment in the study (67.6 months from initial AML diagnosis). The retrospective analysis of the pooled outcomes for AML patients who underwent a transplant in the article published in Bone Marrow Transplantation indicates that the median OS from the time of transplant is approximately 26 months.
- In June 2021, the Company reported encouraging updated clinical data from the Phase I open-label investigator-sponsored clinical trial of GPS in combination with the anti-PD-1 therapy nivolumab (Opdivo) in patients with MPM, who harbor relapsed or refractory disease after having received frontline standard of care multimodality therapy. For the four evaluable patients, all of whom had the epithelioid and/or sarcomatoid variant and have received and progressed with, or are refractory to, frontline pemetrexed-based chemotherapy, the average OS was 35.3 weeks with a median OS of 35.4 weeks at a median follow-up of 35.4 weeks. Overall survival for relapsed/refractory patients receiving standard of care (pemetrexed, a chemotherapy) is approximately 28 weeks. Average progression-free survival (PFS) was 8.8 weeks with a median PFS of seven weeks at a median follow-up of 35.4 weeks. The safety profile of the GPS-nivolumab combination was similar to that seen with nivolumab alone, with the addition of only low-grade, temporary

local reactions at the GPS injection site, which was consistent with previous clinical studies of GPS.

- In June, the Company reported updated clinical data and immune response profiles from the basket study of GPS in combination with the anti-PD-1 therapy pembrolizumab (Keytruda) for treating WT1+ advanced ovarian cancer. Of the 11 evaluable patients, 66.7% were refractory to or had failed their second-line therapies and 33.3% had failed third-line or later therapy and all patients were resistant to the standard of care platinum-based therapy. Overall survival for patients receiving standard of care platinum-based therapy is approximately nine to 12 months. The median OS among the patients in this trial is not yet known as all patients remained alive at the time of analysis, which exceeds nine months. In an ad hoc analysis of the clinical outcomes for the cohort of 11 patients, the disease control rate, or DCR, which is the sum of overall response rate and rate of stable disease, was 63.6% with a median follow-up of 15.4 weeks. At the time of follow-up analysis, median PFS was 11.8 weeks. The safety profile of the GPS-pembrolizumab combination was similar to that seen with pembrolizumab alone, with the addition of only low-grade, temporary local reactions at the GPS injection site which was consistent with previous clinical studies of GPS.
- In May 2021, the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent application covering the use of GPS in combination with checkpoint inhibitor therapies for treatment of WT1-expressing cancers.

#### Corporate and Financial Highlights for the Second Quarter 2021:

- In June 2021, the Company received a \$1 million milestone payment from 3D Medicines Inc., its licensee for development and commercialization of GPS in the Greater China territory.
- In June 2021, the Company was included in the Russell Microcap® Index. Membership in the Russell Microcap® Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes.

#### Financial Results for the Second Quarter 2021:

Licensing revenue: Licensing revenue was \$1.9 million for the second quarter of 2021 and \$7.6 million for the first half of 2021 which consists of the recognition of revenue from the Company's license agreement with 3D Medicines. The Company did not record any licensing revenue for the first half of 2020.

R&D Expenses: Research and development expenses for the second quarter of 2021 were \$3.5 million, as compared to \$2.3 million for the same period in 2020. Research and development expenses for the first half of 2021 were \$7.7 million as compared to \$4.1 million for the same period in 2020. The increase was primarily due to

an increase in clinical trial expenses related to the Company's Phase 3 REGAL clinical trial of GPS in AML patients and a ramp up of the manufacture of clinical trial materials and registration batches of GPS, a technology transfer to a new contract manufacturer, and clinical drug supply purchase costs in the EU in preparation for opening sites and enrolling patients in EU countries.

**G&A Expenses:** General and administrative expenses for the second quarter of 2021 were \$2.8 million, as compared to \$2.0 million for the same period in 2020. General and administrative expenses for the first half of 2021 were \$6.4 million, as compared to \$4.2 million for the same period in 2020. The increase was primarily due to amortization expense associated with the capitalized contract acquisition costs of the 3D Medicines license agreement as well as an increase in legal fees as compared to the same period in 2020 during which the majority of legal expenses were offset by a reimbursement credit.

**Net Loss:** Net loss attributable to common stockholders was \$4.6 million for the second quarter of 2021, or a basic and diluted loss per share attributable to common stockholders of \$0.30, as compared to a net loss attributable to common stockholders of \$4.4 million for the same period in 2020, or a basic and diluted loss per share attributable to common stockholders of \$0.66. Net loss attributable to common stockholders was \$7.0 million for the first half of 2021, or a basic and diluted loss per share attributable to common stockholders of \$0.47, as compared to a net loss attributable to common stockholders of \$8.6 million for the same period in 2020, or a basic and diluted loss per share attributable to common stockholders of \$1.32.

**Cash Position:** As of June 30, 2021, cash and cash equivalents totaled approximately \$29.9 million.

#### Upcoming Investor Symposium

The Company will host a virtual investor symposium on its lead asset, GPS, on Tuesday, August 17, 2021, from 1:00 p.m. to 2:00 p.m. ET.

The event will focus on the Company's clinical program for GPS, including additional details on its recently released clinical data, as well as the significant unmet need in AML, the indication being studied in the GPS Phase 3 REGAL study. SELLAS management will be joined by leading cancer researcher, M. Yair Levy, M.D., Director of Hematologic Malignancies at the Baylor University Medical Center, and member of the REGAL Steering Committee.

To attend the live video webcast, please **register** or email KCSA Strategic Communications at **[SELLAS@kcsa.com](mailto:SELLAS@kcsa.com)**.

#### 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, 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, nelipepimut-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](http://www.sellaslifesciences.com).

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. Opdivo® is a registered trademark of Bristol Myers Squibb, and is not a trademark of SELLAS. The manufacturer of this brand is not affiliated with and does not endorse SELLAS or its products.

#### 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 ovarian cancer, MPM and AML, and the potential for GPS as a drug development candidate. 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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SELLAS LIFE SCIENCES GROUP, INC.  
 CONSOLIDATED STATEMENTS OF OPERATIONS  
 (Amounts in thousands, except share and per share data)  
 (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Licensing revenue	\$ 1,900	\$ —	\$ 7,600	\$ —
Operating expenses:				
Cost of licensing revenue	100	—	200	—
Research and development	3,456	2,280	7,740	4,144
General and administrative	2,797	1,987	6,358	4,187
Total operating expenses	<u>6,353</u>	<u>4,267</u>	<u>14,298</u>	<u>8,331</u>
Operating loss	(4,453)	(4,267)	(6,698)	(8,331)
Non-operating income (expense), net:				
Change in fair value of warrant liability	(28)	(16)	(59)	19
Change in fair value of contingent consideration	(134)	(143)	(263)	(281)
Interest income	2	1	4	25
Total non-operating expense, net	<u>(160)</u>	<u>(158)</u>	<u>(318)</u>	<u>(237)</u>
Net loss	(4,613)	(4,425)	(7,016)	(8,568)
Deemed dividend arising from warrant modifications	—	—	—	(78)
Net loss attributable to common stockholders	<u>\$ (4,613)</u>	<u>\$ (4,425)</u>	<u>\$ (7,016)</u>	<u>\$ (8,646)</u>
Per share information:				
Net loss per common share attributable to common stockholders, basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.66)</u>	<u>\$ (0.47)</u>	<u>\$ (1.32)</u>
Weighted-average common shares outstanding, basic and diluted	15,270,288	6,717,900	15,074,887	6,546,440

SELLAS LIFE SCIENCES GROUP, INC.  
 CONSOLIDATED BALANCE SHEETS  
 (Amounts in thousands, except share and per share data)  
 (Unaudited)

	ASSETS	June 30, 2021	December 31, 2020
Current assets:			
Cash and cash equivalents		\$ 29,917	\$ 35,302
Restricted cash and cash equivalents		100	100
Stock subscription receivable		2,240	—
Contract asset		—	1,128
Prepaid expenses and other current assets		2,318	395
Total current assets		<u>34,575</u>	<u>36,925</u>
Operating lease right-of-use asset		812	896
In-process research and development		5,700	5,700
Goodwill		1,914	1,914
Deposits and other assets		623	614
Total assets		<u>\$ 43,624</u>	<u>\$ 46,049</u>
	LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:			
Accounts payable		\$ 2,276	\$ 4,657
Accrued expenses and other current liabilities		1,781	1,913
Operating lease liability		182	166
Deferred revenue		—	5,600
Total current liabilities		<u>4,239</u>	<u>12,336</u>
Operating lease liability, non-current		721	825
Deferred tax liability		239	239
Warrant liability		114	55
Contingent consideration		4,896	4,633
Total liabilities		<u>10,209</u>	<u>18,088</u>
Commitments and contingencies (Note 6)			
Stockholders' equity:			
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; Series A convertible preferred stock, 17,500 shares designated; no shares issued and outstanding at June 30, 2021 and December 31, 2020		—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized, 15,873,941 and 14,254,554 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively.		2	1
Additional paid-in capital		158,333	145,864
Accumulated deficit		<u>(124,920)</u>	<u>(117,904)</u>
Total stockholders' equity		<u>33,415</u>	<u>27,961</u>
Total liabilities and stockholders' equity		<u>\$ 43,624</u>	<u>\$ 46,049</u>

Source: SELLAS Life Sciences Group, Inc.