



NEWS RELEASE

# SELLAS Life Sciences Provides Business Update and First Quarter 2022 Highlights

4/5/2022

- In-licensed Next-Generation, Highly Selective CDK9 Inhibitor -
- Closed Underwritten Public Offering with Gross Proceeds of \$25 Million -
- Appointed Robert Francomano as Chief Commercial Officer -
- Completed Enrollment in Phase 1/2 Study of Galinpepimut-S (GPS) in Combination with Merck's KEYTRUDA® -
- IND Application in China for Phase I Study of GPS Approved by China's NMPA -
- Shareholder Update Call on Wednesday, April 6 th at 8:30 a.m. Eastern Time -

NEW YORK, April 05, 2022 (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 therapies for a broad range of cancer indications, today provided a business update and overview of activity in the first quarter of 2022.

"The first quarter of 2022 has been transformative for SELLAS as we have significantly enhanced our clinical pipeline with the in-license from GenFleet Therapeutics (Shanghai), Inc. ("GenFleet") of global rights outside of Greater China for GFH009, a highly selective small molecule cyclin-dependent kinase 9 ("CDK9") inhibitor. At the same time, we have continued to progress our lead asset, galinpepimut-S ("GPS"), which is currently being tested in clinical trials for acute myeloid leukemia ("AML"), malignant pleural mesothelioma ("MPM") and relapsed/refractory metastatic ovarian cancer," said Angelos M. Stergiou, MD, ScD. h.c., President and Chief Executive Officer of SELLAS. "We also

strengthened our balance sheet with the closing of a public offering, underwritten by SVB Leerink and Cantor, which will support the continued development of GPS and our ongoing and planned studies for GFH009. We view the addition of GFH009 as a strategic fit to our overall clinical development plans.”

Dr. Stergiou continued, “GFH009 provides us with an opportunity to expand further into the market for AML therapeutics covering not only the maintenance phase of the disease, which is the indication being studied for GPS in the REGAL trial, but also active disease by combining GFH009 with venetoclax and azacitidine. GFH009 has shown a strong synergy with venetoclax in preclinical models, and we believe it has the potential to improve response to venetoclax or possibly convert resistance to venetoclax into a response. Furthermore, we have an opportunity with GFH009 to address additional indications and tumor types, including the very important pediatric market of soft tissue sarcomas – positive results from this program could ultimately provide the basis for a rare pediatric disease priority voucher. Additionally, GenFleet plans to conduct numerous Phase 2 clinical trials for hematological malignancies in China. The data generated by these trials will effectively help us to analyze and identify additional indications in which to launch pivotal studies in our own territories. This parallel development in different indications allows both companies to leverage a much broader body of both safety and efficacy data thus potentially significantly accelerating clinical development.”

“As we continue to progress toward commercialization with GPS, we were thrilled to announce that Robert Francomano joined the SELLAS team in March as Chief Commercial Officer. Robert brings to SELLAS more than 25 years of biopharmaceutical experience, with the majority of time spent in the hematology/oncology therapeutic area, making him a strong addition to our management team,” Dr. Stergiou concluded.

Pipeline Update:

#### Galinpepimut-S (GPS)

- Phase 3 REGAL Study: The Company is continuing to activate and enroll patients in additional sites in the United States, Europe, and Asia. As has been the case with many of its peer companies, the Company has continued to observe that COVID-19 related delays have impacted its projected timeline for the REGAL study. Under the Company’s current planning assumptions, which take into account the Company’s best estimates of potential delays due to COVID-19 as well as input by its external statisticians and experts, the Company believes that enrollment for the REGAL study will be completed in late 2022 or early in the first quarter of 2023 and the planned interim analysis will occur by the end of the first half of 2023, provided that its statistical assumptions and assumptions regarding the impact of COVID-19 on the operations of clinical sites as well as the duration of the pandemic remain unchanged. Because this analysis is event driven, it may become available at a different time than currently expected.

- Phase 1/2 GPS Study in Combination with Merck's KEYTRUDA®: In February 2022, the Company completed enrollment in the Phase 1/2 clinical trial of GPS in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in second or third line Wilms Tumor-1 (WT1)(+) relapsed or refractory metastatic ovarian cancer. Data from 15 patients will be examined by mid-2022, with final data analysis for all evaluable patients expected by the end of 2022.
- Phase I GPS Study in China: In March 2022, an IND application to initiate the first clinical trial in China for GPS was approved by China's National Medical Products Administration which triggered a milestone payment of \$1 million, expected to be received by the Company in the second quarter of 2022. The IND, for a small Phase I clinical trial investigating safety, was submitted by SELLAS' partner in China, 3D Medicines Inc. ("3D Medicines"). 3D Medicines expects to initiate the trial by mid-2022.
- Manufacturing Improvements : In the fourth quarter of 2021, the Company's contract manufacturer for GPS, Lyophilization Services of New England, Inc. (LSNE), manufactured a new regulatory standard drug product batch which entailed further process improvements, which were agreed upon by the FDA. The new manufacturing batch met all the release criteria and, to date, has shown favorable stability data on already known long-term conditions (-20°C) as well as newly accelerated conditions (5°C and 25°C). Both long-term and accelerated stability data are monitored to confirm that all drug product parameters are within the acceptance criteria. This optimized batch, based on the data to date, may ultimately allow for GPS to be stored in 5°C to 25°C conditions versus -20°C, which would be more optimal for supply chain and logistical reasons.
- New Patent Allowance: In February 2022, the U.S. Patent and Trademark Office issued a Notice of Allowance for a patent application covering certain WT1-targeting peptides, in combination with other molecules such as other peptides and immunomodulating compounds, useful for treatment of WT1-expressing cancers. This patent application covering WT1-targeting peptides linked to other molecules, which complements the Company's existing composition of matter patents covering GPS peptides (which expire in 2033 not including any potential extensions), is expected to grant later this year, and will have a patent term that extends to at least 2026.

#### GFH009

- On March 31, 2022, the Company and GenFleet, a clinical-stage biotechnology company developing cutting-edge therapeutics in oncology and immunology, announced that the companies entered into an exclusive license agreement that grants rights to SELLAS for the development and commercialization of GFH009, a highly selective CDK9 inhibitor, across all therapeutic and diagnostic uses worldwide outside of Greater China (mainland China, Hong Kong, Macau and Taiwan).

- GFH009 is currently in a Phase 1 clinical trial in China and the United States which is planned to enroll approximately 80 patients including an expansion part 2. The fourth of six doses is currently being studied in this dose-escalation study. To date, stable disease has been observed in three patients, and a bone marrow blast decreased from 40% to 20% was observed in one AML patient at the 9 mg dose level, which is the third of the six dose levels to be studied in the Phase 1 trial.
- Following completion of the Phase 1 clinical trial and achievement of a maximum tolerated dose, SELLAS plans to commence a Phase 2 clinical trial of GFH009 in combination with venetoclax and azacitidine in AML patients with active disease, likely by the end of the second quarter of 2023. The Company also plans to commence a Phase 1/2 basket clinical trial of monotherapy GFH009 in pediatric soft tissue sarcomas, including Ewing's sarcoma and rhabdomyosarcoma, in late 2022 or early 2023, which it expects to complete by the end of 2023. Positive results from this program could ultimately provide the basis for a rare pediatric disease priority voucher.

#### Nelipepimut-S (NPS)

- Since 2018, based on promising data from a cohort of patients with triple negative breast cancer ("TNBC") from a Phase 2b investigator sponsored clinical trial of the combination of trastuzumab (Herceptin®) plus NPS in HER2 low expressing breast cancer patients in the adjuvant setting, the Company has been seeking out-licensing opportunities for NPS focused on the future clinical development of NPS in TNBC. After extensive effort, the Company has concluded that continued efforts to outlicense NPS for further development for breast cancer alone are unlikely to result in a licensing transaction commensurate with the value of the asset which the Company believes is due to the changing market for breast cancer therapies, the scope, cost and timeline for a Phase 3 trial which would satisfy regulatory requirements for the TNBC indication and the failure, in 2016, by the Company's predecessor, Galena, of the Phase 3 clinical trial of monotherapy NPS in breast cancer. The Company is continuing its out-licensing strategy focusing on the potential for NPS in other cancer indications.

#### Corporate Updates:

- Underwritten Public Offering: On April 5, 2022, the Company closed an underwritten public offering of 4,629,630 shares of its common stock and accompanying warrants to purchase up to 4,629,630 shares of common stock at a combined public offering price of \$5.40 per share and accompanying warrant providing gross proceeds to the Company of \$25.0 million before deducting underwriting discounts and commissions and offering expenses. The warrants to purchase shares of common stock have an exercise price of \$5.40 per share, are immediately exercisable and will expire five years from the date of issuance.

- Cash Position: As of December 31, 2021, cash and cash equivalents totaled approximately \$21.4 million.
- Enhanced Leadership Team:
  - In March 2022, SELLAS appointed Robert Francomano as Chief Commercial Officer.
  - In January 2022, the Company promoted John Burns to Senior Vice President, Finance, and Chief Accounting Officer.
  - In the fourth quarter of 2021 and the first quarter of 2022, the Company added heads of manufacturing and quality control/quality assurance functions.
- Settlement of Legacy Galena Litigations:
  - In February 2022, SELLAS received the final court approval of the settlement of securities litigation relating to the Company's predecessor, Galena, marking the end to all litigation related to activities of Galena. In November 2021, SELLAS received final court approval of the settlement of three derivative suits relating to the securities litigation.

#### Webcast Information

The Company will host a shareholder update call tomorrow morning, Wednesday, April 6, 2022, at 8:30 a.m. eastern time featuring remarks by Angelos M. Stergiou, MD, ScD. h.c., President and Chief Executive Officer of SELLAS.

To attend the live video webcast, please **register** or email KCSA Strategic Communications at **SELLAS@kcsa.com**.

#### About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics 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. GPS has potential both as a monotherapy and in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. The Company is also developing GFH009, a small molecule, highly selective CDK9 inhibitor, which is licensed from GenFleet Therapeutics (Shanghai), Inc. for all therapeutic and diagnostic uses in the world outside of Greater China.

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 clinical development of GPS and GFH009, the potential for GPS and GFH009 as drug development candidates for various cancer indications, alone and in combination with other therapeutic agents and the timing for the reporting of data analyses. 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 31, 2022 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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