

# ELLAS

## SHAREHOLDER LETTER

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### April 28, 2020

### **To My Fellow Shareholders:**

As I write this letter, we are in unprecedented times and all of us at SELLAS wish you and your families to remain safe and healthy. Although we are now all living through this COVID-19 pandemic, I hope to convey a theme of growth and transformation at SELLAS as we are further advancing our clinical programs and remain diligent in our business development/licensing efforts. We greatly appreciate your dedication to and support of our company over the years and we are confident that 2020 will demonstrate that your loyalty was well-placed.

The global COVID-19 pandemic has caused us all to adapt to a new reality. As SELLAS has always functioned as a semi-virtual company, we have been able to navigate the transition to a new way of doing business quite seamlessly. I'm pleased that our small number of employees, working from their homes, have been able to continue our business operations uninterrupted. At the same time that we are collectively fighting this pandemic, millions of people are still confronting the scourge of cancer and we cannot, and will not, allow COVID-19 to stand in the way of our mission of developing therapeutic cancer vaccines for patients with a broad range of cancers. Against this backdrop, we remain clear in our mission and vision to develop and deliver complex and innovative treatments for patients battling cancer. We are doing our best to manage those elements of our business that we believe we can control – progressing our assets, generating clinical and immunobiological data, executing on clinical development and progressing with business development opportunities. As of this writing, the three ongoing clinical trials for our lead clinical candidate, galinpepimut-S (GPS), have not been materially impacted. And our business development efforts seeking a licensee for our Phase 3 ready nelipepimut-S (NPS) are also continuing. As such, we plan to continue to report data from our programs as it becomes available throughout the remainder of 2020 and into 2021.

Our highly innovative and, by design, engineered immunotherapeutic, GPS, with artificially introduced single point amino acid sequence mutation in two peptides, which we licensed in from Memorial Sloan Kettering Cancer Center, has genuinely exciting clinical data across many indications. However, as you might have seen in other biotechnology companies with promising drugs, the initial excitement about these treatments, particularly in the immunotherapy and cancer vaccine space, is frequently followed by a healthy dose of skepticism before many of these modalities ultimately prove themselves to be beneficial in effecting key treatment paradigm changes across indications. In my eighteen years in the biotechnology industry, including substantial time in cancer vaccine development, I have seen this cycle play out many times.

We have strong belief in our mission but that type of skepticism is just one of the challenges we have faced since SELLAS became a publicly traded company a little over two years ago, and 2019 was no exception. As we were finally settling the issues that we had inherited from the predecessor company that we had merged into, we began to explore various strategic alternatives that could provide us with the capital we needed for our trials, including a possible merger, acquisition or financing, among other alternatives. In June 2019, we were pleased to close on a public offering of shares of our common stock, raising approximately \$13.5 million of new capital, net of offering expenses.

This financing was an extremely important event that enabled us to kick off the pivotal Phase 3 REGAL clinical trial for GPS in



patients with acute myeloid leukemia (AML) who are in second remission. In the fall, we engaged a CRO, Worldwide Clinical Trials, to help us conduct the REGAL study. This was an important event as Worldwide provides us with the support we need to efficiently conduct this pivotal Phase 3 study. By working diligently throughout the Fall, we were able to activate the first clinical trial site for the REGAL study in December, another important milestone for SELLAS.

In January 2020, we completed a registered direct sale of common shares which added approximately \$6 million, net of expenses, in new capital to our balance sheet. Since then, among other things, we have been busy conducting all of the necessary preparations required to activate additional clinical trial sites in the United States and Europe. As we are still in this early stage of the study, much of this work has been able to continue despite the impact of COVID-19. Please note that we intend to provide meaningful updates as warranted as the REGAL study progresses but we do not expect to provide ongoing updates on enrollment rates.



In addition to commencing the **REGAL study, there** was a lot of other exciting activity for GPS in 2019 and early 2020:

### 🗰 In July 2019

> We dosed the first patient in the Phase 1/2 open-label, non-comparative, multicenter, multi-arm study of GPS in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with selected WT1-positive advanced cancers, including both both hematologic malignancies and solid tumors.

This study, which is being conducted under a Clinical Trial Collaboration and Supply Agreement with Merck (known as MSD outside the United States and Canada), will assess the efficacy and safety of the combination, with exploratory long-term follow-up for overall survival and safety. The study will enroll up to approximately 90 patients at up to approximately 20 centers in the United States. The initial tumor types being studied are primarily ovarian cancer (second or third line) followed at this point by colorectal cancer (third or fourth line) with up to approximately 40 patients in total in these two indications, with the remaining indications being AML (in patients having achieved partial response as their best hematological response after four cycles of therapy with hypomethylating agents), triple negative breast cancer (TNBC) (second line), and small cell lung cancer.

Richard Maziarz, M.D., Medical Director of the Adult Blood and Marrow Stem Cell Transplant & Cellular Therapy Program at the Knight Cancer Institute and Professor of Medicine at Oregon Health and Science University in Portland, OR, and Roisin O'Cearbhaill, M.D., Assistant Attending Physician in Gynecologic Medical Oncology Service at the Memorial Sloan Kettering Cancer Center (MSK), are serving as co-principal investigators of the study.



### 🛅 In November 2019

very well attended with over 350 investors present at the event or on the webcast.

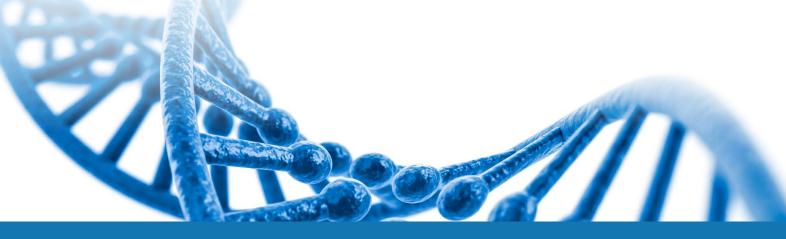
The KOLs who spoke included Dr. Hagop M. Kantarjian, M.D., Chair of the Department of Leukemia and Associate Vice President for Global Academic Programs at the University of Texas MD Anderson Cancer Center and principal investigator of SELLAS' Phase 3 clinical trial of GPS in acute myeloid leukemia and who was recently named as the head of the REGAL Trial Steering Committee; Javier Pinilla-Ibarz, M.D., Ph.D., Senior Member of the Malignant Hematology & Immunology Program and Director for Immunotherapy for Malignant Hematology at the H. Lee Moffitt Cancer Center; David A. Scheinberg, M.D., Ph.D., Vincent Astor Chair and Chairman of the Molecular Pharmacology Program, Founder and Chair of the Center for Experimental Therapeutics and former Chief of Leukemia at Memorial Sloan Kettering Cancer Center and a member of the SELLAS Board of Directors; and Jeffrey S. Weber, M.D., Ph.D., Deputy Director of the Perlmutter Cancer Center and Co-Director of the Melanoma Research Program at the NYU Langone Cancer Center.

### 📖 Also in November

positive patients with ovarian cancer in second- or third-line remission.

Topline data from this study at 10 months had been earlier presented at the American Society of Clinical Oncology (ASCO) annual meeting in June 2018. This follow-up data now shows 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 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. Furthermore, no new serious adverse events were noted during the longer follow-up period. We believe this data continues to support the development of GPS in combination with PD-1 inhibitors.



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> We hosted our first R&D investor event: "Galinpepimut-S (GPS) and the Next Generation of Cancer Immunotherapy." We were very proud to have a renowned group of Key Opinion Leaders (KOLs) discuss the promise of GPS and the REGAL study. The event was

> We were very excited to report follow-up data from our Phase 1 clinical trial of GPS in combination with nivolumab to treat WT1

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### 🛗 In February 2020

We commenced an investigator-sponsored clinical trial (IST) of GPS in combination with Bristol-Myers Squibb's anti-PD-1 therapy, nivolumab (Opdivo®), in patients with malignant pleural mesothelioma (MPM), which is being conducted at Memorial Sloan Kettering Cancer Center (MSK).

The Phase 1 open-label clinical study is enrolling patients with MPM who harbor relapsed or refractory disease after having received frontline standard of care multimodality therapy with study drug provided by both SELLAS and Bristol-Myers Squibb. The principal investigator for the study is Dr. Marjorie G. Zauderer, MD, Co-Director, Mesothelioma Program, Team Lead, Thoracic Disease Management Team, and Assistant Attending Physician in the Division of Thoracic Oncology, Department of Medicine at MSK. As of this writing, three patients have been dosed in this IST.

### 🛗 Also in February

We reported more exciting follow-up data. This final follow-up data is for our Phase 1/2 study of GPS in patients with acute myeloid leukemia (AML) in second complete remission (CR2). This is the same indication as the REGAL study. The final data shows a median overall survival (OS) of 21.0 months, at a median follow-up of 30.8 months, in patients receiving GPS therapy. Those AML CR2 patients being treated with best standard care only had a median OS of 5.4 months. This demonstrates a statistically significant difference (p-value < 02) for the patients treated with GPS. Final analysis also showed that GPS therapy continued to be well-tolerated throughout the study.</p>

With the growing body of positive data on the efficacy of GPS, we are focusing all of our clinical development resources on its continued development. Accordingly, we are actively continuing our efforts to maximize value for nelipepimut-S (NPS) through an out-license of the program. Following the feedback we recently received from a Type C review with the FDA, we have now finalized the design and plan for a Phase 3 registration-enabling study of NPS in combination with trastuzumab for the treatment of patients with TNBC in the adjuvant setting after standard treatment. With NPS' demonstrated potential and a Phase 3 trial plan ready to be implemented, we believe that NPS could be an attractive asset for many companies.

Our plans for NPS are further supported by the intriguing preliminary data from the VADIS study. The antigen-specific immune response data from this Phase 2 randomized IST of NPS in women with ductal carcinoma in situ (DCIS) of the breast showed that the relative frequency of NPS- specific CD8 cytotoxic T-lymphocytes as a percentage (NPS-CLT%) was twice as large in the NPS- treated patients, and the relative magnitude of change in NPS-CTL% mean values in NPS-treated patients over time was an 11-fold increase. Data from the Phase 2b study focusing on the combination of NPS plus trastuzumab for the adjuvant treatment of women with 'classically defined' HER2+ (i.e., IHC HER2 3+/HER2/neu FISH-amplified) breast cancer with very high-risk features, to prevent or delay the occurrence of relapse/recurrence of the disease, is expected before year-end 2020.

In early 2020, Dragan Cicic, MD, joined us as SVP, Clinical Development. Dr. Cicic has spent several years overseeing clinical trials, both early and late stage, in hematologic malignancies, primarily in AML. He also has led the global clinical development of targeted solid cancer biologicals and was involved in the development of novel checkpoint inhibitors as well as other innovative biological and small molecule drug candidates at his previous biotech company. Our former Chief Medical Officer, Dr. Nick Sarlis, transitioned to a consultant role last year but is still actively supporting certain of our projects. We thank Nick for his great service to SLS during his time as CMO, as well as in his current capacity at SELLAS, and welcome Dragan to the SELLAS team.

Our key objectives for 2020 include progressing enrollment of our REGAL study and reporting interim data from our Phase 1/2 basket trial in collaboration with Merck & Co., that combines GPS with Keytruda (pembrolizumab) as well as data from the MPM IST study of GPS with Opdivo (nivolumab). While uncertainty abounds for all of us during the COVID-19 pandemic, we are committed to maintaining a laser focus on achieving our goals for 2020 as well as continuing our mission to develop novel immunotherapeutic treatments for blood cancers and solid tumors that can extend patients' lives while maintaining quality of life.

We have had many obstacles over the last two years but we have overcome them all while always delivering on our core mission – the possibility to help patients in need and to change their world, as well as the world of their loved ones and caregivers, and prolong survival with our assets.

We cannot succeed without you, our shareholders, and all of us here at SELLAS thank you for your continuing support and for being an integral part of this journey.



Sincerely,

**Angelos M. Stergiou, MD, ScD h.c.** President and Chief Executive Officer

Keytruda® is a registered trademark of Merck & Co. (known as MSD outside the United States and Canada). Opdivo® is a registered trademark of Bristol Myers Squibb.

### **Forward-Looking Statements**

This letter and the annual report contain 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 clinical development of for GPS, including the timing of clinical results, and the potential for GPS as a drug development candidate, and its business development efforts for NPS. 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 and business strategy, 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 13, 2020 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 expect



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