

# **Company Overview** NASDAQ: SLS January 2022

## Forward Looking Statements



This presentation contains forward-looking statements. Such forward-looking statements can be identified by the use of the words "expect," "believe," "will," "anticipate," "estimate," "plan," "project" and other words of similar import. The forward-looking statements in this presentation include, but are not limited to, statements related to the potential of our clinical candidates as therapeutic options for various cancers, the general development of the Company's product candidate pipeline and anticipated milestone dates, and the effects of the Company's approach to cancer treatment. 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. These risks and uncertainties are described more fully under the caption "Risk Factors" in the in SELLAS' Annual Report on Form 10-K filed on March 23, 2021 and in its other filings with the Securities and Exchange Commission. Other risks and uncertainties of which SELLAS is not currently aware may also affect SELLAS' forward-looking statements. The forward-looking statements herein are made only as of the date hereof. SELLAS undertakes no obligation to update or supplement any forwardlooking 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.

#### Overview



**SELLAS** is a late-stage clinical biopharmaceutical company focused on the development of **novel cancer immunotherapies** for a broad range of cancer indications.

- Lead product galinpepimut-S (GPS): highly novel and engineered immunotherapy targeting the Wilms Tumor 1 (WT1) antigen
  - > Discovered and licensed from Memorial Sloan Kettering Cancer Center
- ➤ GPS: Ongoing Phase 3 pivotal trial (REGAL study) for acute myeloid leukemia (AML) in patients achieving second complete remission (CR2)
- ➤ GPS: Phase 1/2 combination studies with anti-PD1 drugs collaboration agreement with Merck (KEYTRUDA®) in various tumor types and an IST study with Memorial Sloan Kettering Cancer Center and Bristol Myers Squibb (OPDIVO®) in metastatic pleural mesothelioma
- Out-licensing opportunity with second product candidate, nelipepimut-S (NPS): HER2-directed cancer immunotherapy with potential for the treatment of patients in the maintenance setting with triple negative breast cancer

## Galinpepimut-S (GPS): Changing the face of Immunotherapy





#### Pivotal Phase 3 Trial Underway in CR2 AML Patients (REGAL study)

- Monotherapy AML maintenance after Second Complete Remission (CR2)
- Interim read-out expected in second half of 2022 (as long as there are no COVID-related delays)
- Potential launch first half of 2024
- Orphan Drug Designation (US and EU) and Fast Track status
- Phase 2 results:
  - GPS reaching **21.0** months median Overall Survival vs. **5.4** months standard of care (p < 0.02).



#### ✓ Validated Wilms Tumor 1 (WT1) Target

- #1 ranked cancer antigen by the NCI
- GPS targets tumors that overexpress the WT1 protein



#### Innovative, First-in-Class Technology Licensed from Memorial Sloan Kettering

- Highly engineered immunotherapy designed to boost immunogenicity and break tolerance
- Applicable to the majority (90%) of human HLA types
- Activation of both CD4+ (memory) and CD8+ (tumor killing) cells
- Sustained remission

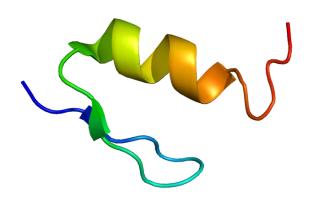


#### Broad Applicability in I/O Treatment Setting and Strong IP Position

- Potential to be used as **monotherapy or in combination** with other I/O agents in multiple **solid and hematological** tumor types; two studies of GPS in combination with PD1 inhibitors ongoing
- Composition of matter patent to at least 2033

## WT1: Nuclear Transcription Factor with Oncogenic Properties





Wilms Tumor 1 Protein

Leukemia

Review | Published: 15 March 2007

A tumor suppressor and oncogene: the WT1 story

L Yang, Y Han, I

**SCIENTIFIC REPORTS** 

Leukemia 21, 8

Article | Open Access | Published: 09 March 2015

Wilms' tumor 1 (WT1) expression and prognosis in solid cancer patients: a systematic review and meta-analysis

Xiao-wei Qi, Fan Zhang, Hong Wu, Jun-lan Liu, Bei-ge Zong, Chuan Xu & Jun Jiang

Scientific Reports 5, Article number: 8924 (2015) | Cite this article

Top Ranked Cancer Antigen by the **National Cancer Institute** (NCI)<sup>1</sup>

Potential to treat **20 or more** cancer types creates a **large potential market** for WT1 targeting therapies

Broadly detectable in AML, where it is densely and almost universally expressed (97%). It is also expressed in multiple solid tumors and cancer stem cells

Highly expressed and presented in cancer cells, enabling recognition and killing by specifically immunized T-cells

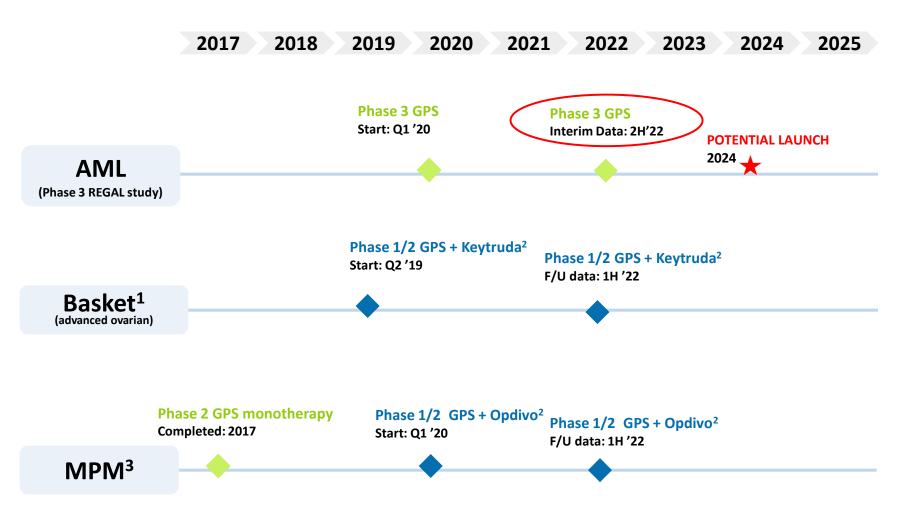
Intracellular oncofetal antigen, WT1 not found appreciably in adult tissues, which lowers potential off-target toxicity

Does **not** down-regulate or become mutated frequently

Sources: Gaiger, Leukemia. 1998; 2. Dao & Scheinberg, Best Pract Res Clin Haematol. 2008; 3. Nishida & Sugiyama, Methods Mol Biol. 2016; NED: no evidence of disease Notes: 1. 'The Prioritization of Cancer Antigens: A National Cancer Institute Pilot Project for the Acceleration of Translational Research' Cheever et al; Clin Cancer Res., 2009.

## Near-Term Value Creation Milestones for Pipeline











## Differentiated Immunotherapy Using Heteroclitic Technology



'Heteroclitic' peptides are engineered to have an artificially introduced single point amino acid (AA) sequence mutation:
i.) peptide binds with a higher affinity, ii.) breaks tolerance to the native sequence and iii.) stimulates stronger T cell response

### **GPS**

"Heteroclitic" multivalent peptide chains addressing 25 WT1 epitopes

- 4 peptides of variable lengths (9-22 amino acids)
- 2 native sequences
- 2 synthetic sequences with single AA mutations

# Peptide sequences (position) WT1-A1: \*YMFPNAPYL (126–134) 9-mer 427 long: RSDELVRHHNMHQRNMTKL (427–445) 19-mer 331 long: PGCNKRYFKLSHLQMHSRKHTG (331–352) 22-mer 122A1 long: SGQA\*YMFPNAPYLPSCLES (122–140) 19-mer

#### Heteroclitic peptides increase immune response

- Synthetic sequence binds with higher strength (affinity) to the HLA molecules, generating stronger immune response
- Increases chance of generating clonal T-cell population with recognition of at least one peptide, and a clinical response against the tumor
- Breaks tolerance to the native tumor sequence
- Generates a response against the native sequence found in the tumor cells
- Spurs **multi-epitope**, **broad cross-reactivity** along the full length of the WT1 protein

# Production of both CD4 and CD8 WT1-specific activated cells

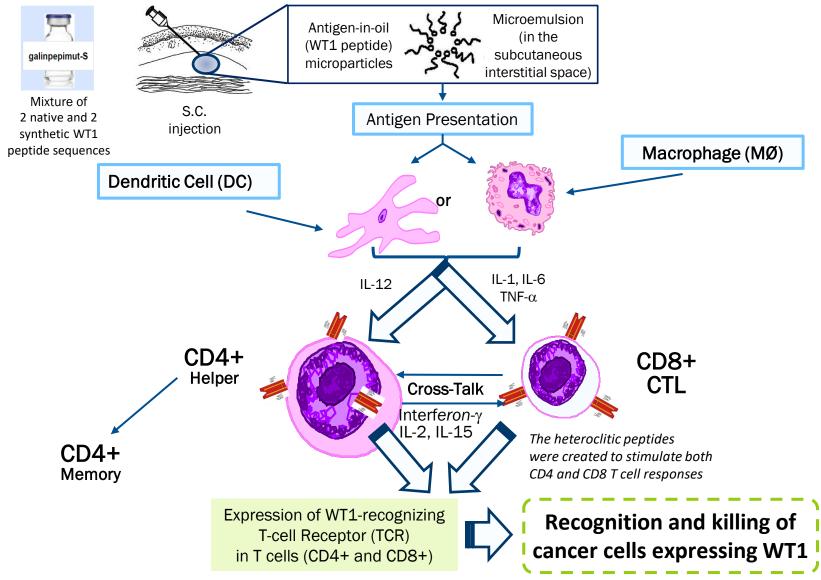
- Native sequences designed to activate CD4+
- Synthetic sequences designed to active CD4<sup>+</sup> and CD8<sup>+</sup>

#### Specificity across multiple HLA types<sup>1</sup>

- Broad coverage of human HLA allelic variation
- Allows for 'off the shelf' subcutaneous injection use and simple manufacturing process (lyophilized formulation)

#### Mechanism of Action









## Compelling Survival Benefit Seen in AML Patients in CR2 1,2



#### Completed Phase 2 Open-label Study in AML CR2 Patients at Moffitt Cancer Center (MCC)

Median Overall Survival (All Age Patients): GPS vs SOC\*

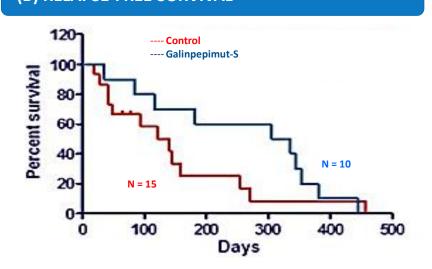
21.0 months vs 5.4 months p < 0.02

# (A) OVERALL SURVIVAL 120 100 100 100 100 100 N=10 Days

Relapse Free Survival (All Age Patients): GPS vs SOC\*

## 10.5 months vs 4.3 months





<sup>\*</sup> Standard of Care

## Further Validation of GPS efficacy of AML: CR1 Phase 2 study



#### Phase 2 Open-label Clinical Study in AML CR1 Patients

#### Overall Survival (All Age Patients): GPS vs SOC

67.6 months vs 17.5 - 25 months

Overall Survival (>60 Years Patients):GPS vs SOC

35.5 months vs 9.5 - 15.8 months

#### **Key Points:**

- Pre-specified primary endpoint of 3 year OS > 34% was met in 47% of patients. AML historical OS at 3 years is ~25%<sup>1</sup>
- Phase 2 survival with GPS in elderly (>60 yr) AML patients in CR1 far exceeds that seen with historical comparators (statistically significant), even allogeneic stem cell transplant
- 88% of patients dosed with GPS had an antigen specific immune response to any of the 4 GPS peptides of either CD4+ or CD8+; 64% had a persistent, mainly CD4+ response at both early and late time points
- CD4+ responses seen across all HLA-Class II subtypes tested

# Phase 3 Trial Underway in Niche AML CR2 Patient Population within Rare AML Disease – GPS Broad AML Applicability

















**GPS** 

#### **Patient Journey**

#### AML Diagnosis (~77,000 Incident Pts WW)<sup>1</sup>

97% of AML Patients
Express WT1

**NASDAQ: SLS** 

# 1<sup>st</sup> Line Therapy (80% patients)<sup>2</sup>

- Chemotherapy
- Targeted Therapy
- Radiation therapy
- Surgery

# Complete Remission 1 (CR1) (50-55% patients)<sup>2</sup>

- CR/MRD<sup>3</sup> determined by biopsy
- Consolidation (maintenance) therapy: chemotherapy; targeted therapy continuation; allo/auto SCT
- Phase 1 and 2 data generated in CR1 AML supports GPS potential label expansion in this setting

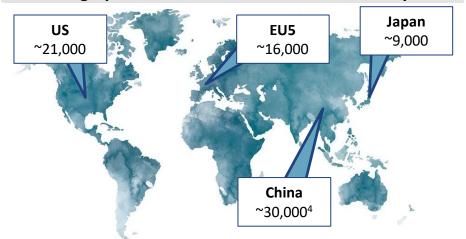
#### 1<sup>st</sup> Relapse; 2<sup>nd</sup> Line Therapy (30-35% patients)<sup>2</sup>

- Chemotherapy
- Targeted Therapy
- Allo SCT
- Post-transplant patients could potentially benefit from GPS treatment<sup>5</sup>

# Complete Remission 2 (CR2) (12-15% patients)<sup>2</sup>

- CR/MRD as determined by biopsy
- Consolidation (maintenance) therapy: chemotherapy, allo-SCT; targeted therapy
- GPS initial label phase 3 trial ongoing in CR2 AML

#### Geographic Incident Adult AML Cases Annually<sup>1</sup>

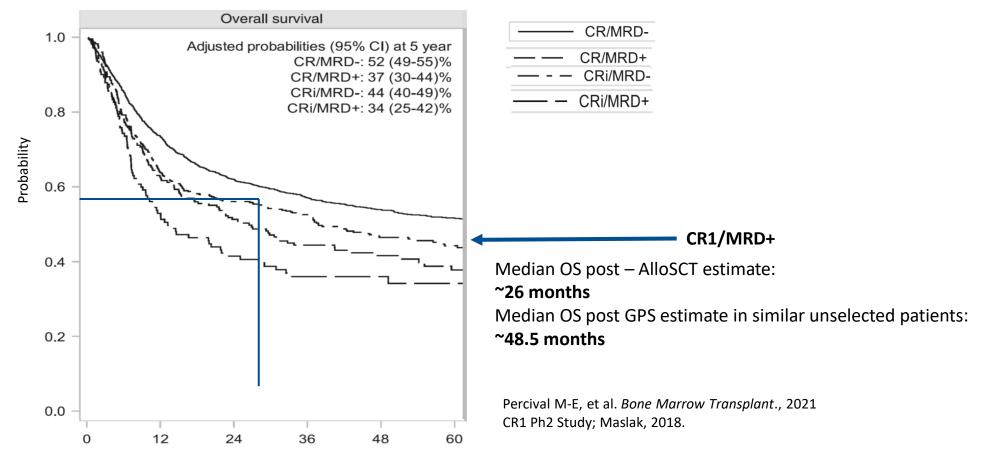


- **GPS** not only has potential for CR2 patients but could be equally important in the CR1 patient population
- Pool of addressable patients further enhanced by fact that CR1 patients who undergo bone marrow transplant (BMT) who are less likely to benefit from it (whom GPS could potentially significantly extend survival) - MRD positive patients – can be identified
- Further potential expansion: patients in complete remission with incomplete peripheral blood recovery (CRi); addition of GPS to any potential maintenance drugs

# New Data Highlight GPS Opportunities in Bone Marrow Transplant (BMT) Settings



- BMTs cure approximately 50% of patients if they have no MRD and approximately 33% of patients with MRD
- Median OS for patients with MRD: approximately one year if they did not have complete peripheral blood recovery
  after the treatment and approximately two years if they had a complete peripheral blood recovery
- In Phase 2 CR1 GPS study, patients had complete responses and were MRD positive but not eligible for transplant; median survival was 48.5 months even without transplant, approximately 2x longer than same category of patients who received transplant



# Design of Phase 3 Registration Enabling Study in CR2 AML Patients (REGAL)



Target Population and Inclusion Criteria

Treatment:
Open Label; Randomised Multi-center Phase 3 Trial

Endpoints and Interim
Analysis

N = 116

Patients >18 years old

#### Stratification axes:

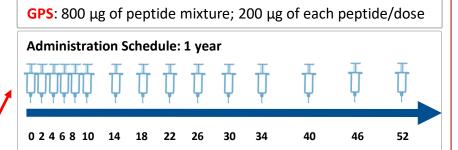
- CR2 vs CRp2 status
- Cytogenetics risk category
- Duration of CR1 (12 months)
- MRD status

CR2/CRp2 AML Patients post-2L therapy (excluding agents for targeted molecular aberrations)<sup>1</sup>

Ineligible/unable to undergo imminent Allogeneic Stem Cell Transplant (ASCT)

Global Study: > 100 clinical sites

#### Cohort 1



#### **Primary Endpoint: Overall Survival**

- · At least 90% powered
- Assumed Hazard Ratio (HR) of 0.52 based on a median OS of 10.0 months (GPS) vs 5.4 months (BAT)
- To declare statistical significance: either a HR of <0.60 at interim analysis, or a HR of <0.675 at final analysis

#### Cohort 2

R

1:1

**Best Available Therapy (BAT)** 

**Clinician's choice of 4 regimens** (Observation; HMAs and/or Ventoclax and/or Low-dose Ara-C

**Interim Analysis:** SAP provides for planned interim safety and futility analysis after first **80 events** 



U.S. & Global Lead

Hagop Kantarjian, MD
Distinguished Professor
Head, Dept. of Leukemia
M.D. Anderson Cancer Center
Houston, Texas

# Steering and Data Monitoring Committee For Phase 3 REGAL Clinical Trial



Steering Committee	Position
Hagop Kantarjian, M.D.	Chair of the REGAL Steering Committee, Professor and Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center, and Principal Investigator at MD Anderson for the multi-center Phase 3 REGAL study
Javier Pinilla-Ibarz, MD, PhD	Director of Immunotherapy for Malignant Hematology at the H. Lee Moffitt Cancer Center and member of the SELLAS Scientific Advisory Board
Moshe Yair Levy, M.D.	Director of Hematologic Malignancies at the Texas Oncology - Baylor Charles A. Sammons Cancer Center
Data Monitoring Committee	Position
Miguel-Angel Perales, M.D.	Chair of REGAL DMC. Chief, Adult Bone Marrow Transplant Service at Memorial Sloan Kettering Cancer Center (MSKCC)
Miguel-Angel Perales, M.D.  Stephane de Botton, M.D.	•





# GPS Monotherapy Has Shown Impressive Clinical Trial Results in MPM and MM



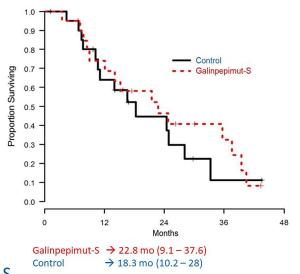
Blinded, Randomized Controlled Phase 2 in Metastatic Pleural Mesothelioma (MPM), After Surgery and 1L Therapy<sup>1</sup>

#### **Key Points:**

- GPS increased overall survival vs. control group. Study n=41
- GPS induced both CD8+ and CD4+ T-cell activation, with frequencies of 66.7% and 50% respectively
- GPS was well tolerated; adverse events were mainly low grade reactions at the site of injection
- Successful End-of-Phase 2 meeting with FDA

Median Overall Survival (All Patients): GPS vs SOC

#### 22.8 months vs 18.3 months



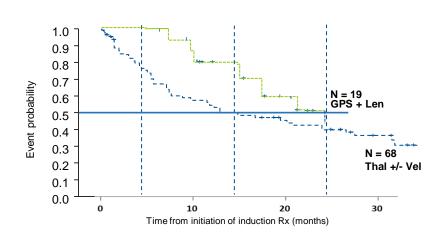
Open-label Phase 2 Study in <u>Multiple Myeloma (MM)</u> Patients, in Maintenance Setting with Lenalidomide after 1<sup>st</sup> Successful

#### **Key Points:**

- Inclusion criteria also mandated patients had baseline high risk cytogenics and remained MRD positive after transplant
- GPS increased progression free survival vs. historical control (Thalidomide +/- Velcade maintenance therapy in same patient population as GPS treatment). Study n = 20
- Progression free survival (PFS) rate at 12 months: 81%; PFS rate at 18 months: 62%; Overall survival (OS) at 18 months: 88%. Median OS not yet reached

Median Progression Free Survival (All Age Patients): GPS vs SOC

#### 23.6 months vs 14.0 months



# GPS Has Demonstrated Activity and Is Well Tolerated in Combination with Checkpoint Inhibitors in WT1 expressing Solid Tumors



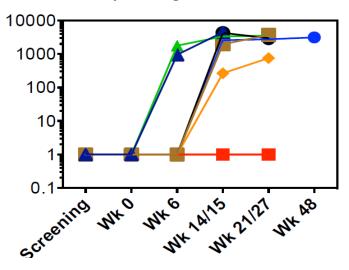
Open-label Phase 1 GPS + Nivolumab in Minimum Residual
Disease (MRD) Negative, WT1+
Ovarian Cancer Patients After 1st or 2nd Salvage
Chemotherapy

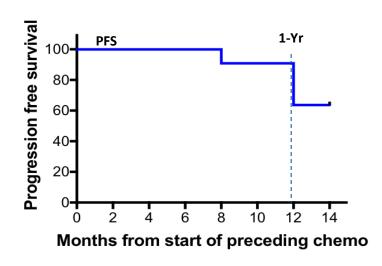
#### **Key Points:**

**NASDAQ: SLS** 

- 1. Primary Endpoint met: GPS + nivolumab was well tolerated in study (n=11). Most frequent treatment related adverse events (TRAEs): injection site reaction, joint pain and fatigue. None above Grade 1
- 2. Secondary Endpoint met: WT1-specific IgG (against all 4 GPS peptides) observed in 86% of patients (wks 6 27). CD4<sup>+</sup> and CD8<sup>+</sup> T cell responses also observed (wks 6 15)
- 3. Exploratory Endpoint: Landmark 1-year PFS rate = 70% in pts who received >1 dose of GPS + nivolumab (n=10). Historical PFS rates<sup>2-4</sup> do not exceed 50% in this setting<sup>1</sup>
- 4. Exploratory Endpoint: Landmark 2-year PFS rate = at least 30% in pts who received >1 dose of GPS + nivolumab (n=10)<sup>5</sup>. Historical PFS rates<sup>2-4</sup> range between 3-10% in this setting<sup>5</sup>

#### WT1-specific IgG titers over time





# Two Ongoing Trials of GPS in Combination With Checkpoint Inhibitors

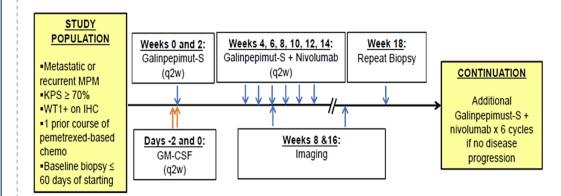


# Open-label Phase 2a Basket Study GPS + Pembrolizumab

#### **Key Points:**

- Inclusion of patients 18 years or older (n=90) with any of 5 different tumor types treated concurrently with pembrolizumab and GPS. WT1 expression determined by immunohistochemistry with advanced measurable disease at entry
- Current prioritization on ovarian (second or third line) arm of trial
- Primary endpoint: Safety, RECIST (ORR) in solid tumors, morphological CR in AML. Secondary Endpoint: Duration of Response
- Exploratory endpoints: PFS, OS, ORR, % MRD negative, immune response and pembrolizumab PD correlates
- Interim data as of June 30, 2021 shows disease control rate of 63.6% with median follow-up of 15.4 weeks; all patients alive at time of median followup; immune response data showed significant induction of WT1-specific T-cell immune response.

Open-label Phase 1 Investigator Sponsored Study (IST ) of GPS + Nivolumab in relapsed/refractory MPM post 1L SOC Therapy (Pemetrexed) at MSKCC



 Interim Data (as of June 24, 2021) shows median overall survival of 35.4 weeks in patients treated with combination therapy for at least one month; median overall survival in relapsed/refractory patients with standard of care is approximately 28 weeks.

# Broad Patent Coverage on Composition of GPS and Combination with Check-Point Inhibitors



#### Patents on each of the 4 GPS peptides and their use:

- US: Coverage to 2033 with potential 5 years extension, with 14 years max term post approval
- Europe: Coverage to 2027 with potential 5 years extension, in individual countries
- Australia and Canada: Coverage to 2026 with potential 2 years extension
- China: No patent coverage

# Patents on GPS when used with new WT1 peptides ("GPS-Plus") having expanded haplotype for Asian populations

- US: Coverage to 2034 with potential 5 years extension, with 14 years max term post approval
- Europe: application allowed; will expire 2034 with potential 5 years extension, in individual countries
- China, Australia, Japan: Coverage to at least 2034

#### Patent application covering 7-peptide WT-1 immunotherapy composition and methods of use

- US: provisional application filed April 2019
- International (PCT) application filed April 2020 which will allow for filing in 150+ member states including China, with potential coverage to at least 2040

#### Patent and patent applications filed on combination with CPIs:

- US: patent granted June 15, 2021; coverage to 2036 with potential 5 years extension, with 14 years max term post approval
- Europe (application pending): Coverage to 2036 with potential 5 years extension, in individual countries
- China (application pending): Coverage to 2036 with potential 5 years extension
- Japan, Korea, Australia, Canada and Hong Kong (applications pending): Coverage to 2036





## License Agreement with 3D Medicines, Inc.



#### **Exclusive License Granted to 3D Medicines in December 2020:**

- Sublicensable, royalty-bearing license to develop, manufacture and commercialize GPS and heptavalent GPS (GPS-Plus)
- All therapeutic and diagnostic uses
- Territory: mainland China, Hong Kong, Macau and Taiwan (Greater China)

#### **Financial Terms:**

- Upfront cash payment of \$7.5 million upon entry of agreement
- Additional potential development, regulatory and commercial milestones totaling up to \$194.5 million
  - \$2 million achieved and received in 1H'21 relating to technology transfer
- Tiered royalties based upon percentage of annual net sales of licensed products (GPS) in the Greater China territory ranging from high single to low double digits





## NPS: HER2 Immunodominant Peptide



- NPS contains immunodominant peptide derived from the extracellular region of HER2 protein
  - Administered as intradermal injection
- Target indication: in combination with trastuzumab for triple negative breast cancer (TNBC) patients in the adjuvant setting to prevent recurrence
  - Patients who are hormone receptor-negative and HER2 1+/2+ by IHC
    - 30% of HER2 1+/2+ breast cancer patients
    - 15% of all breast cancer patients
  - No FDA-approved targeted therapies for this indication
- Phase 2b data showed clinically and statistically significant improvement in disease-free survival rate for TNBC cohort at 24 months
  - Clinically meaningful and statistically significant difference in triple-negative breast cancer (TNBC) cohort (n= 98) with a HR of 0.26 (p=0.013) in favor of NPS + Herceptin combination
    - Landmark analysis of DFS rates at 24-mo: 75.2% reduction in relative risk of recurrence or death (active vs. control arm)
    - **72.5% relative reduction in the number of clinically detectable relapses** (p=0.004; active vs. control arm)
  - Phase 3 registration-enabling study design finalized
- Currently focused on business development efforts to maximize value through an out-license of the program





# **Experienced Management Team and Board of Directors**



Manager	ment Team	Position	Prior Experience/Affiliations
	Angelos Stergiou, M.D., ScD h.c.	President, CEO & Board Director	PAION Biovest International ACCENTIA ACCENTIA ACCENTIA ACCENTIA MATERIALISMO ACCENTIA ACCENTI
	Dragan Cicic, M.D.	SVP, Clinical Development	Actinium Pharmaceuticals, Inc.
	Barbara A. Wood	EVP, General Counsel & Corporate Secretary	OPHTHOTECH(os1) pharmaceuticals
	John T. Burns, CPA	SVP, Finance, and Controller and Chief Accounting Officer	GALENA BIDPHARMA
Board of	Directors <sup>1</sup>	Position	Prior Experience/Affiliations
3 6	Jane Wasman	Board Chair, Nominating and Governance Committee Chair	ACØRDA THERAPEUTICS Schering-Plough
3	John Varian	Audit Committee Chair	XOMA VERSARTIS
3	Robert Van Nostrand	Compensation Committee Chair	(osi) pharmaceuticals  ACHILLION  Intra-Cellular Therapies
	Dr. David Scheinberg	Science Committee Chair	Memorial Sloan Kettering Cancer Center  Progenics Pharmaceuticals

# Scientific Advisory Board – World Renowned Experts in Immunotherapy And Oncology



Name		Position	
OP.	Jeffrey Weber, M.D., Ph.D Chair	Deputy Director of the Perlmutter Cancer Center, Co-director of the Melanoma Research Program at the New York University (NYU)-Langone Cancer Center	
	Jedd D. Wolchok, M.D., Ph.D.	Chief, Melanoma & Immunotherapeutics Service, Memorial Sloan Kettering Cancer Center (MSKCC)	
	Alexander M.M. Eggermont, M.D.	Chief Scientific Officer, Princess Maxima Center for Pediatric Oncology, Utrecht, NL Former Director General, Institut Gustave-Roussy Cancer Campus - Grand Paris, Villejuif, FR	
	Larry W. Kwak, M.D., Ph.D.	Vice President and Deputy Director of the City of Hope Comprehensive Cancer Center; Associate Director Cancer Center Translational Research & Developmental Therapeutics for the City of Hope National Medical Center	
	Javier Pinilla-Ibarz, M.D.	Director of Immunotherapy for Malignant Hematology at the H. Lee Moffitt Cancer Center	
	Sattva Neelapu, M.D., Ph.D.	Professor and Deputy Department Chair at the Department of Lymphoma and Myeloma, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center	
	Guenther Koehne, M.D., Ph.D.	Chief, Bone Marrow Transplantation and Hematologic Oncology, Miami Cancer Institute	

## **Key Takeaways**



#### ✓ **Significant milestones** for GPS expected through 2022

- Phase 3 REGAL trial for AML CR2 patients
  - O Interim data expected 2H 2022 (as long as there are no COVID-related delays)
- Phase 1/2 basket study in five additional indications in combination with PD1 inhibitor
  - Additional interim data expected early 2022
- Phase 1 study in MPM in combination with PD1 inhibitor
  - Additional interim data expected early 2022

#### ✓ GPS: Targets WT1, the #1 immunotherapy target of National Cancer Institute

- Potentially applicable to >20 cancer types
- Orphan designation and fast track status

#### ✓ GPS: a sophisticated, highly differentiated immunotherapeutic

- 130+ patients treated in trials to date
- Good tolerability, consistent and notable signals of clinical benefit
- Heteroclitic peptides increase immune response
- Production of both CD4 and CD8 WT1-specific activated cells



# Thank You!

For additional information, please contact:

SELLAS Life Sciences Group, Inc. (Nasdaq: SLS)

917-438-4353

info@sellaslife.com

SELLAS@kcsa.com