



#### FORWARD LOOKING STATEMENTS



This presentation contains forward-looking statements. You can identify such forward-looking statements 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 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 exhibit 99.1 in the in SELLAS' Current Report on Form 8-K filed on July 18, 2018 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 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.

### LATE-STAGE CANCER IMMUNOTHERAPY COMPANY



Pivotal Phase 3 Development Programs	<ul> <li>Galinpepimut-S (GPS) WT1 peptide vaccine</li> <li>Acute myeloid leukemia (AML) with orphan drug designation (ODD) and fast track status</li> <li>Nelipepimut-S (NeuVax, NPS) HER-2 peptide vaccine</li> <li>Combination NPS + trastuzumab in triple negative breast cancer (TNBC) with fast track status</li> </ul>
Innovative Technology	<ul> <li>GPS incorporates heteroclitic technology to preserve and increase WT1 antigenicity</li> <li>Multivalent to address 25 WT1 optimally selected epitopes; NCl's #1 ranked cancer antigen</li> <li>Induces CD4 and CD8 activation across multiple tumor types without HLA type restrictions</li> <li>NPS targets immunodominant HER2 peptide fragment</li> </ul>
Robust Pipeline	<ul> <li>GPS has demonstrated efficacy as monotherapy and in combination with other IO therapies across multiple tumor types in earlier stage trials</li> <li>Multiple myeloma (ODD and fast track status), malignant pleural mesothelioma (ODD and fast track status), and ovarian cancer in combination with IO</li> <li>E39 peptide vaccine (folate binding protein)</li> <li>Efficacy observed in Phase 1/2a study in ovarian and endometrial cancer</li> </ul>
Broad and Strong Intellectual Property	<ul> <li>GPS: Composition of matter protection to 2033</li> <li>NPS: Method of use protection to at least 2028 (additional applicationss pending)</li> <li>E39 peptide: Method of use protection to at least 2036 (additional applications pending)</li> </ul>
Experienced Leadership Team	<ul> <li>Leadership with significant experience in vaccine and immunotherapy development, as well as deep operational and business development expertise</li> <li>Board members include highly seasoned pharma and biotechnology executives and innovator of GPS; SAB includes global leaders in oncology</li> </ul>

# **MANAGEMENT TEAM**



NAME		POSITION	PRIOR EXPERI	ENCE / AFFILIATIONS		
-	Angelos Stergiou, M.D., ScD h.c.	President, Chief Executive Officer	PAION	= BIOPHAKI	NIEWAN	UNAL LIFE SCIENCES LOTE
	Nicholas J. Sarlis, M.D., Ph.D., FACP	EVP, Chief Medical Officer	NIH	MD Anderson <del>Cancer</del> Center	SANOFI	Incyte
A	Barbara Wood, J.D.	EVP, General Counsel & Corporate Secretary		PHTHOTECH	<b>(os1)</b> pharn	
	John T. Burns, CPA	VP, Finance & Corporate Controller		GALENA BIOPHARMA	MOSSADAMS	

#### CLINICAL PROGRAM OVERVIEW



#### Galinpepimut-S (GPS): WT1 peptide vaccine

- Acute myeloid leukemia (AML): In an open-label Phase 2 study with older patients (≥60 years; historical control ~12 months) median overall survival reached 35.3 months and 67.6 months across all ages; pivotal Phase 3 study planned
- Malignant pleural mesothelioma (MPM): Blinded, randomized-controlled Phase 2 demonstrated 22.8 months median overall survival compared with 18.3 months with controls; Pivotal phase 3 study planned
- Multiple myeloma (MM): In an open-label Phase 2 study median progression-free survival reached 23.6 months (historical control 14.0 months); median overall survival not yet reached
- Ovarian cancer (with nivolumab): In an open-label Phase 1 study in combination with PD-1 inhibitor (nivolumab) progression-free survival at one year was 70% in patients treated with at least two doses of GPS
- Five tumor types (with pembrolizumab): Open-label, basket-type Phase 1/2 study in combination with PD-1 inhibitor (pembrolizumab) with immune and clinical responses as endpoints in advanced metastatic disease (CRC, SCLC, TNBC, ovarian, AML on hypomethylating agents); initially in AML and ovarian patients; study is enrolling patients

#### Nelipepimut-S (NPS): HER2 peptide vaccine

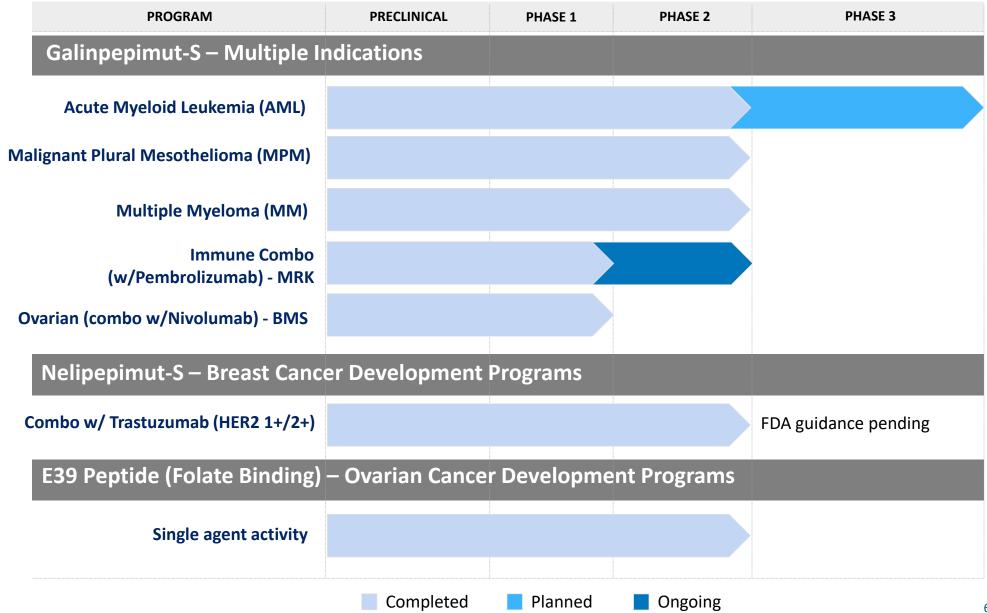
• Triple Negative Breast Cancer (TNBC) (in combination with trastuzumab): Randomized, single blinded Phase 2b resulted in a 75.2% reduction in relative risk of tumor recurrence in the active arm vs. control with a HR=0.26 (p=0.013); pivotal Phase 3 study planned

#### E39: Folate binding peptide vaccine

Ovarian/Endometrial Cancer: Phase 1/2a trial results show disease free survival in patients at optimal dose of E39 improved to 77.9% vs 40.0% for control patients (p=0.013)

#### **DEVELOPMENT PIPELINE**





### ANTICIPATED NEAR-TERM MILESTONES



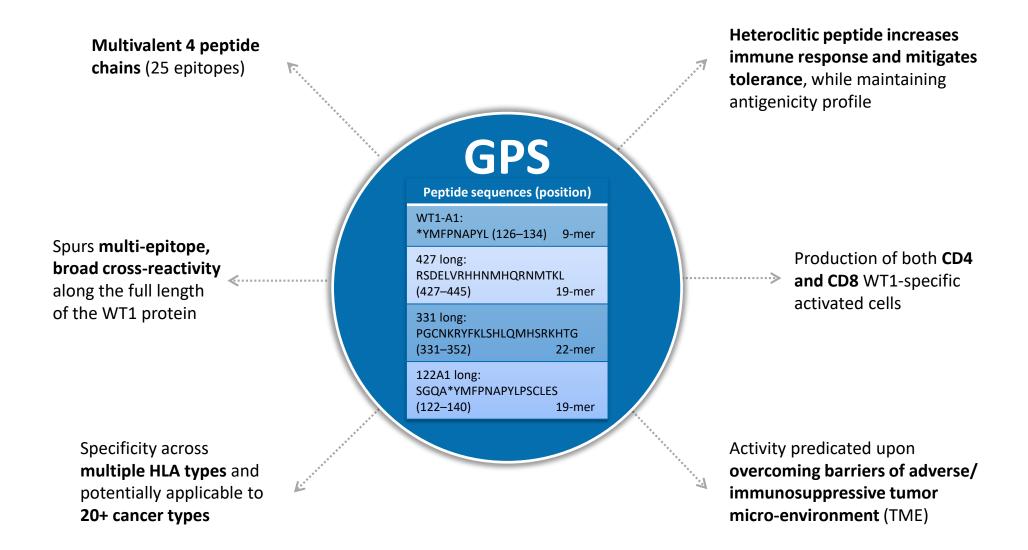
Program	Milestone	Projected Date
NPS	Regulatory guidance from FDA and EMA on further development	Q1 2019
GPS	Start AML Phase 3 randomized trial	Q2 2019
GPS	Interim analysis of Phase 1/2 combination trial with PD-1 inhibitor (pembrolizumab)	Q4 2019
GPS	First Interim analysis of AML Phase 3 randomized trial	Q3 2020





# GPS: NOVEL PEPTIDE ENGINEERED FOR DIFFERENTIATED IMMUNOTHERAPY





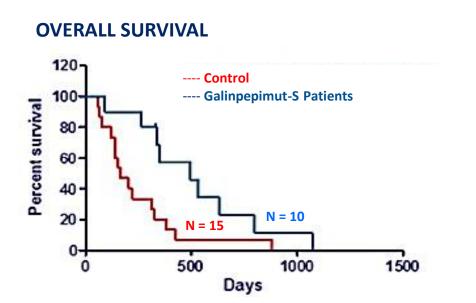
#### POSITIVE PHASE 2 CLINICAL RESULTS IN ACUTE MYELOID LEUKEMIA

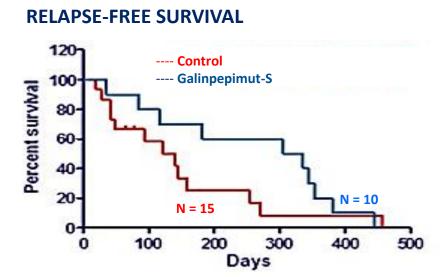


- Primary endpoint of 3-year OS > 34% was met: 47.4%
- Prolonged median overall survival: 67.6 months (all ages)
- Aggregate population of patients  $\geq$  60 years (Phase 3 population): median overall survival (mOS) = **35.3 months** in Phase 2 (vs. SOC of  $\sim$  1 year)
  - Patients ≥ 60 years in CR1 demonstrated statistically significant OS rate
- **88%** of patients had evidence of immune response by either CD8+ or CD4+ reactivity to any of the 4 peptides in GPS after administration
- CD4+ responses seen across HLA-Class II subtypes
- No discernable effect of HLA allelic type expression on clinical outcomes
- No Grade 3 or worse systemic side effects were observed
- Successful End-of-Phase 2 meeting with FDA; finalized Phase 3 program

# INDEPENDENT TRIAL IN AML PATIENTS IN CR2 AT MOFFITT CANCER CENTER (MCC)





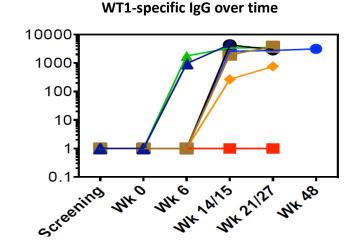


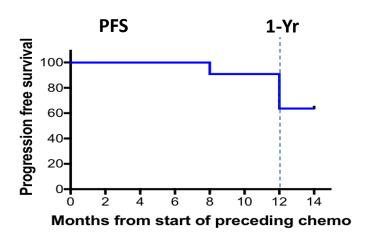
- AML patients receiving > 2 administrations of GPS (n=10) compared to group of paired patients in CR2 contemporaneously treated at MCC during a similar time period (n=15)
- Overall survival (OS) in GPS-treated individuals significantly greater vs.
   the compared group, 16.3 months vs. 5.4 months (p = 0.0175)

#### OVARIAN CANCER TRIAL: GPS + Nivolumab



- Patient Characteristics:
  - N = 11 (open label)
  - 7 pts were in second remission and 4 pts were in third remission
  - Recurrent WT1+ ovarian cancer in 2<sup>nd</sup> (n=7) or greater (n=4) clinical remission after salvage chemotherapy
- Clinical activity
  - Landmark 1-year PFS rate = 64% (ITT group), 70% in pts who received >1 dose of GPS + nivolumab (n=10).
  - Historical PFS rates do not exceed 50% in this setting
- Immune responses
  - WT1-specific IgG observed in 86% of patients (wks 6 27)
  - CD4 and CD8 T cell responses also observed (wks 6 15).
- Safety:
  - Most frequent TRAEs: injection site reaction (G≤1), joint pain (G≤2) and fatigue (G≤2)
  - DLT in one patient, with G3 myositis (incl. cardiac involvement); resolved
    - AE known to be associated with the use of nivolumab.





#### PLANNED PHASE 3 STUDY IN AML



- Successful End-of-Phase 2 Meeting with FDA
  - Agreed: study design, endpoints, statistical analysis and CMC
- Primary endpoint is overall survival; secondary endpoints include LFS, safety, rate of achievement of MRD negativity, antigen-specific T-cell immune response dynamics
- 50 sites in the U.S. and Europe; >100 sites already pre-screened
- Trial population
  - N = 116; adult patients (>18 yrs)
  - AML in second complete remission (CR2; incl. CR2p), ineligible for or unable to undergo allotransplant following physician's choice 2<sup>nd</sup> line antileukemic therapy

#### Trial design

- Open-label; 1:1 randomization, GPS to predefined set of Best Available Therapies (BAT)
- Up to 15 GPS doses in 1 year post-CR2, maximum study duration from LPI: 1.75 years
- 91% power to detect a 92% survival relative difference (10.4 vs. 5.4 months; HR of 0.52)
- One pre-planned interim analyses by DSMB for efficacy after the first 80 events

# PHASE 2A STUDY OF GPS + PEMBROLIZUMAB (KEYTRUDA): MERCK COLLABORATION – PATIENT ENROLLMENT INITIATED



Study

**Endpoints** 

#### **SCHEMA**

- Adult patients (<u>></u>18 yrs)
   with confirmed WT1
   expression (by IHC)
- Presence of technically biopsy-accessible lesions
- CRC: tumor samples genomically tested for microsatellite status (MSS vs MSI)

# N = 10-20 CRC^ 3/4L N = 10-20 OvC 2/3L N = 10-20 SCLC 2L N = 10-15 TNBC 2L AML in PR (HMAs)\*

#### **Galinpepimut-S**

(200  $\mu g$ / peptide x 4  $\rightarrow$  800  $\mu g$ /dose)

**→**Administered SC

Pembrolizumab (Keytruda)

(200 mg every 3 weeks)

→ Administered IV

Treatment continued until disease progression or unacceptable toxicity (up to 111 weeks)

#### **Trial Design:**

- Open-label, 20 U.S. centers, multi-arm combination trial
- N = 90 (total)

#### **Primary Endpoints:**

- Safety
- ORR (RECIST and iRECIST)
- Rates of CR\*, achievement of MRD(-) status (for AML only)

#### **Exploratory Endpoints:**

- PFS, OS
- Immune Response Correlates
  - Peripheral Blood:
  - Tumor tissue (for solid tumors) or bone marrow (for AML)
- Principal Investigators: Dr. Richard Maziarz, Oregon Health and Science University, Dr. Roisin O'Cearbhail, Memorial Sloan Kettering Cancer Center
- 15 active sites expected by mid-March
- Currently 7 patients in screening process for enrollment

ENROLLMENT

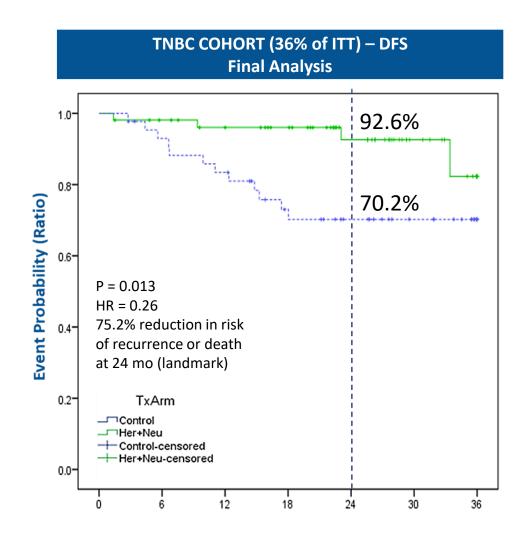




#### PHASE 2B NPS + HERCEPTIN COMBINATION TRIAL RESULTS



- Phase 2b: N = 275 patients
- Two primary study target patient populations
  - Lymph node-positive and triple-negative breast cancer
  - Pre-specified interim analysis by independent DSMB
- 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)
- In vivo T-cell immune responses (IR) by DTH skin testing: time-dependent increase in IR potency vs. earliest data point tested (p=0.000023; active vs. control arm)
- Recommendation from DSMB: expeditiously seek regulatory guidance by the FDA and EMA for further development of NPS + Herceptin in TNBC



Time since first dose of TZ (months)

Median F/U = 26.1 mo





#### FOLATE BINDING PROTEIN-DERIVED E39 PEPTIDE VACCINE



- Novel peptide vaccine approach targeting the folate binding protein (FBP)
  - Incorporates peptide E39 of FBP along with its attenuated version E39' (J65)
  - Induces immunogenicity and decreases the potential for immune tolerance
- Clinical activity in ovarian and endometrial cancer with low expression of FBP
  - Maintenance setting after standard of care therapy
  - No FDA-approved targeted therapies for this population
- Phase 1 trial: active (N=29) vs. contemporaneously monitored controls (N=22) significant improvement in 24-month DFS rate of 55.5% (active) vs. 40.0% (control), p=0.039
  - Patients receiving highest dose of E39 vaccine showed an even greater difference in outcome, with a 24-month DFS of 77.9% (p=0.013)
- Data manuscript submitted; publication expected in 1H 2019





# **BOARD OF DIRECTORS**



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(a)	Jane Wasman	Board Chair, Nominating and Governance Committee Chair	ACØRDA THERAPEUTICS Schering-Plough
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	Stephen Ghiglieri	Board Member, Audit Committee	MedData — hansen NEUROGESX

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NAME		POSITION
	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 at Memorial Sloan Kettering Cancer Center (MSKCC)
	Alexander M.M. Eggermont, M.D.	Director General of Institut Gustave Roussy Cancer Campus Grand Paris, Villejuif, France
	Larry W. Kwak, M.D., Ph.D.	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.	Associate Professor, Department of Lymphoma/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



