



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## **Company Showcase**



## **Moderator & Speakers**





Dan Hargrove, JD

Moderator

Co-Founder & Past President LumaBridge, LLC



**James Barlow, MBA** 

Chief Executive Officer ImmunoGenesis, Inc.



Lance Black, MD, MBID

Chief Clinical Strategy Officer
Prana Thoracic, Inc.



## Speakers, continued





Kirk Dorius, JD

Chief Executive Officer
Atom Mines, LLC



Laura Indolfi, PhD

Founder & Chief Executive Officer
PanTher Therapeutics, Inc.



**Upendra Marathi, PhD, MBA** 

President & Chief Executive Officer
7 Hills Pharma





Company Overview
CPRIT Conference 2023

Laura Indolfi
Founder and CEO
lindolfi@panthertx.com
www.panthertx.com

## **Clinical-Stage Oncology Company Transforming Targeted Treatments**

### **Venture-Backed Start-Up Leveraging Minimally Invasive Procedures**



De-risked lead program

Early clinical evidence that PanTher's lead program, PTM-101, is effective at reducing the size pancreatic tumors



Fast to market potential

FDA supports 505(b)(2) pathway, taking advantage of known and approved active pharmaceutical ingredients



Significant pipeline opportunity

Platform can be applied to numerous drugs where therapeutic potential is limited by safety issues (e.g., approved effective drugs, novel drugs in development)



Leadership position

CEO developed PanTher's novel technology over the past 11 years, which is supported by broad foundational IP with issued claims

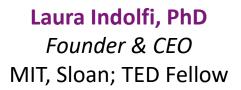


**Financing** 

PanTher is currently funded through 2024 and intends to initiate a Series B financing in Q1 2024.

## Leadership Understands Industry, Know-How, and Drug Development







SVP of Development and Operations



John Edwards
Executive Chair



**Dan Wildman** *Board Member and Strategic Advisor* 







Johnson Johnson

## **Technology Endorsed by Renowned KOLs**



Thomas Clancy
MD, FACS
Surgical Oncologist
Dana-Farber Cancer Institute



Theodor Hong
MD
Radiation Oncologists
Massachusetts General Hospital



Jason Fleming
MD, FACS
Surgical Oncologist
Moffitt Cancer Center



Ching-Wei Tzeng
MD, FACS
Surgical Oncologist
MD Anderson Cancer Center



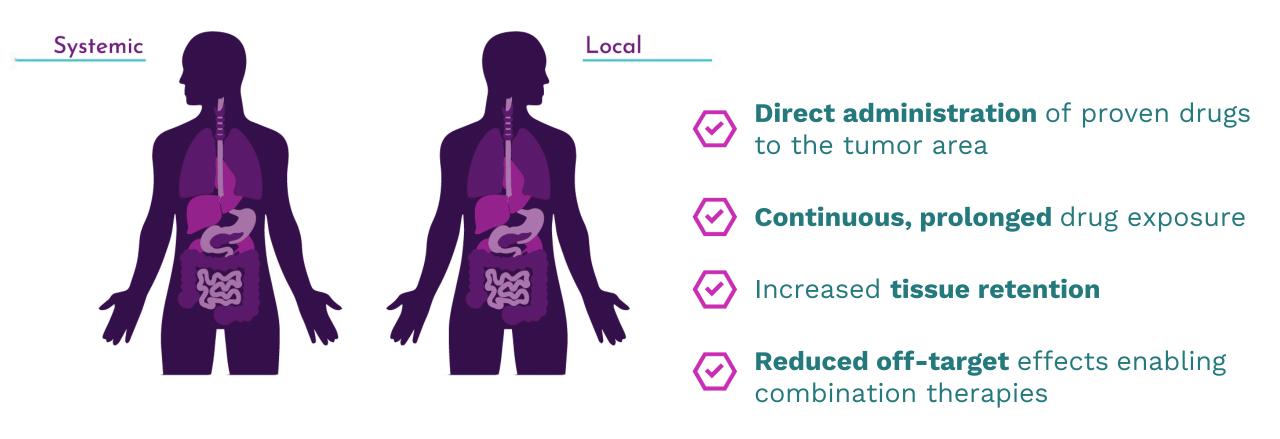






## Sagittari™: Enhancing Clinical Outcomes through Local Treatment

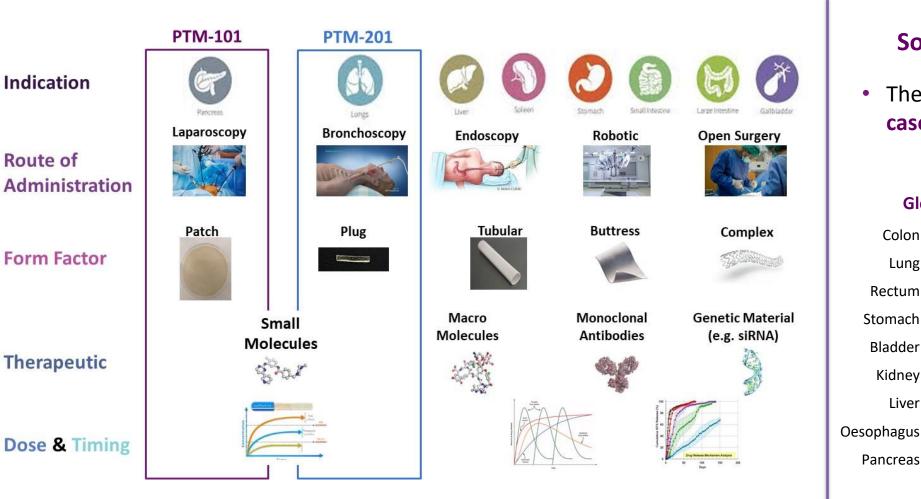
# Unlocking the full potential of oncology drugs by engineering sustained direct-to-tumor treatments



## Sagittari<sup>TM</sup> Yields Modular Customized Solutions

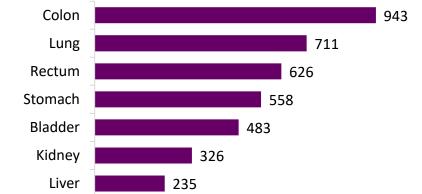
Indication

Route of



#### **Solid Tumor Opportunities**

There are >9 million addressable cases annually indicated for surgery



217

206

**Pancreas** 

**Global Cases Indicated for Surgery (000s)** 

**Every staging / diagnostic procedure is a potential entry point for our platform solutions** 

## PTM-101: ~\$2B Opportunity in Neoadjuvant Pancreatic Cancer

1st Clinical Program

**Route of Administration** 

**Form Factor** 

**Therapeutic** 



## **Lead Indication: Pancreatic Cancer**

- PTM-101 eligible for drug reimbursement at \$25,000+ via J Code
- ~50% of pancreatic cancer patients are eligible for laparoscopy
- Neoadjuvant treatment is a \$1.9
   Billion opportunity in US and EU alone
- Upside: Adjuvant treatments could double the market opportunity

### PTM-101: Lead Product for Pancreatic Cancer

Leverage SOC diagnostic procedure to start early treatment with clinically validated chemo to reduce tumor volume

## **Phase I Clinical Trial Demonstrate Encouraging Results**



Will Physicians Recommend It?



Does It Fit Into Current Treatment Regime?



Is It Safe For Patients?

## Promising early clinical data for first dose cohort

- ✓ Local response demonstrated in initial cohort of patients
- ✓ Excellent safety profile, well tolerated in all patients with no SAEs, no peritonitis, pancreatitis, infection, or hematologic toxicity.
- ✓ No detectable level of drug systemically at any tested timepoint.
- ✓ Minimal increase in OR time for PTM-101 deployment (<20min).
  </p>

## Strong Response in the Direction of Drug Release for all Patients



**Diagnostic CT** 



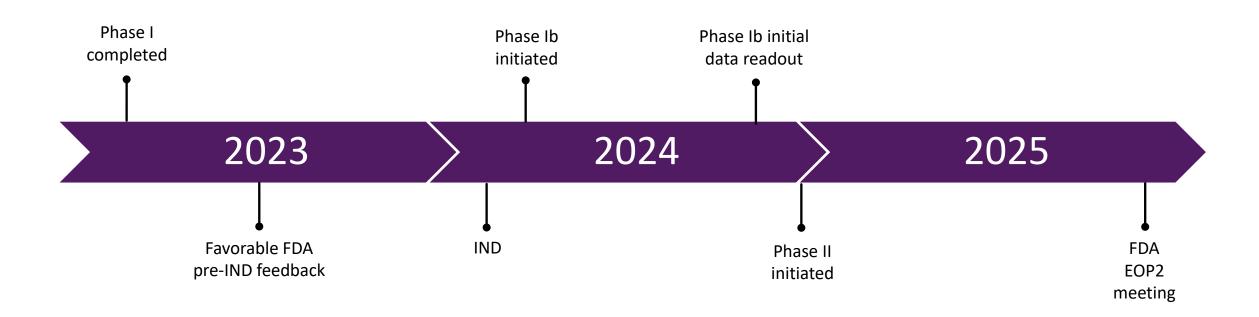
2 weeks Post-Implant



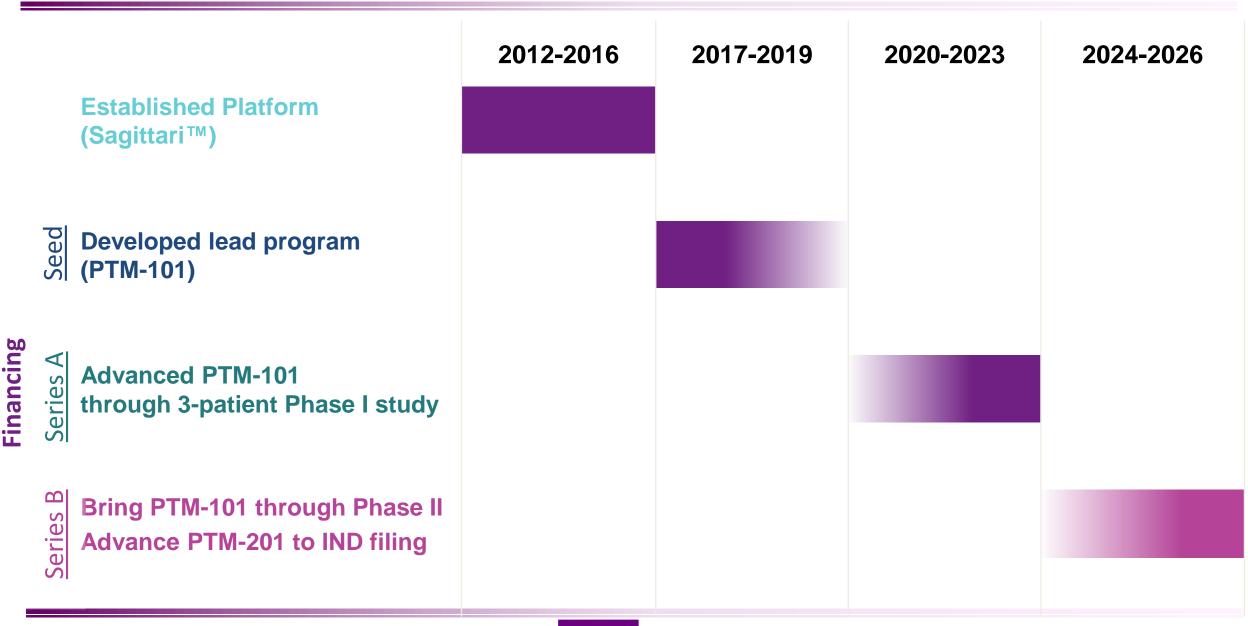
24 weeks Post-Implant

## PTM-101: Development Timeline and Key Milestones

Multiple data readouts and value triggers over next two years



## **Building PanTher: Our History and Plan Ahead**



## **CPRIT-Driven Highlights In the First Year**

> Attract talent to increase skillset and execute on the vision



Leslie S Sloan, PhD SVP of Development and Operations











## Bringing the Fight against Cancer to the Target (and Times Square)





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## 7 Hills has deep roots in Texas



Founded with Local Technology



**Local Executives** 





**Local Capital** 

~\$8 million angel investment

**CPRIT/NIH** 

~\$27 million Sponsored Research

Local Development















Catalent.

## Integrin activation improves immunotherapy



#### **Solid Tumors**

#### **Problem:**

90% of patients resistant to checkpoint inhibitors

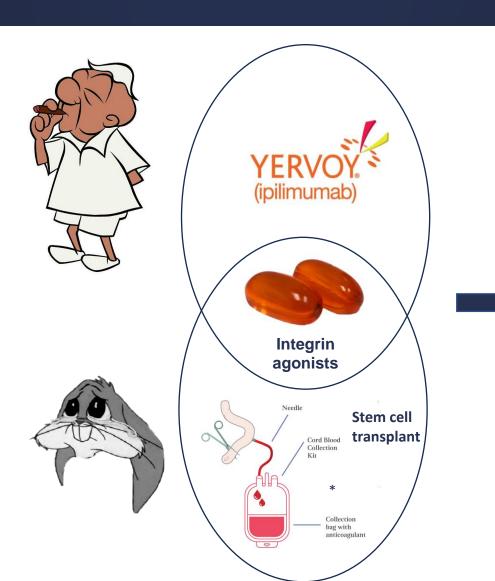
**Solution:** Alintegimod



#### **Problem:**

>70% of patients will not find a match for curative stem cell transplant

Solution: 7HP935





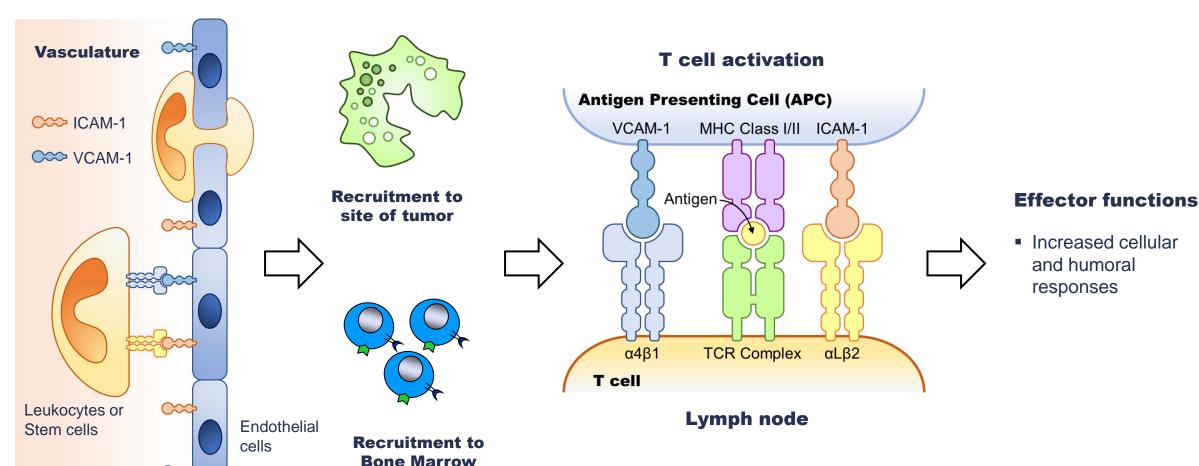
#### **Outcomes**

- Improved patient survival
- Low toxicities
- Low cost

# Integrin mediated cell adhesion is critical in the major steps of an immune response



#### Recruitment



CCC

# Risk diversified pipeline leverages >\$20 million in active non-dilutive funding



PRODUCT	INDICATION	PRE- CLINICAL	IND- ENABLING STUDIES	PHASE Ia	PHASE Ib/IIa
7HP349 Oral Capsules	PD-1 refractory solid tumors	Alintegimod			\$17 mm CPRIT & NIH
7HP935 Oral Capsules	Stem Cell Transplant	7HP935		(\$4 MM)	
7HP577 Oral Capsules	Influenza/Chagas Vaccination	7HP577	\$5 MM NIH		

Time: 1 year

2 years

Total Non-dilutive funds ~\$27 million

3 years

## Problem: No effective treatment options for patients that fail immune checkpoint blockade



#### **Situation**



#### **Solid Tumors**

- >\$30 Billion on PD-1 inhibitors
- >90% of patients progress on PD-1 inhibitors

### Complication

- Ipilimumab + Nivolumab may provide 27% ORR
- Generate new T cells,
- But, ~60% Grade >3 AEs

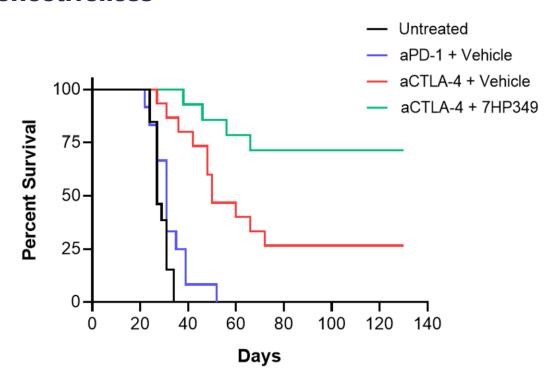
#### 7 Hills Solution

- Alintegimod, a dual α4β1 and αLβ2 agonist
- A means to augment costimulation without added toxicity

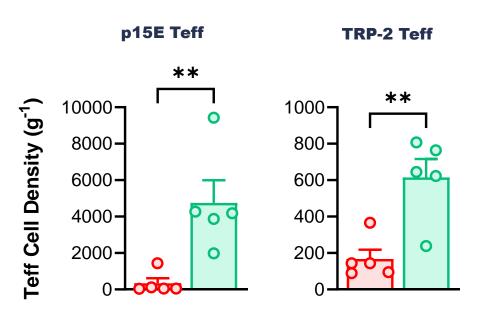
## Solution: Augment Co-stimulation



## **Increase Cancer Immune Checkpoint Inhibitor effectiveness**



## **Increase Generation of New Melanoma Specific T cells**



Hickman et al, J. Clin. Inv. 2022

## Problem: No effective treatment for patients who can't get a bone marrow transplant



#### **Situation**



#### Leukemia

- Mortality of 25 to 50%
- Most common childhood cancer

### Complication

- Myeloablative therapy + Stem cell transplant can be curative
- >70% of patients will not find a matched donor
- Umbilical Cord blood is an alterative source of cells
  - Less restrictive match requirements
  - But, slow to engraft

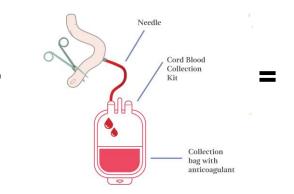
## Solution: Improve access to transplant – improve outcomes



### 7 Hills Stem Cell Therapy Regimen



7HP935 is an  $\alpha$ 4 $\beta$ 1 agonist



An off-the-shelf generic human cord blood hematopoietic stem cell product

#### **Outcomes**

- Immediate availability
- Faster engraftment
- Simple, low cost development path





# Single oral dose of 7HP935 augments stem cell transplant

2 weeks

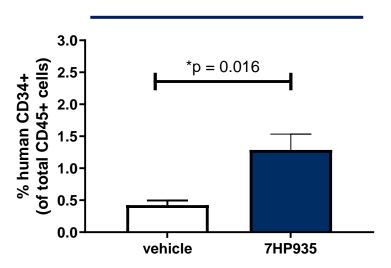


Human CD34<sup>+</sup> cord blood cells plus <u>single oral dose</u> of 7HP935

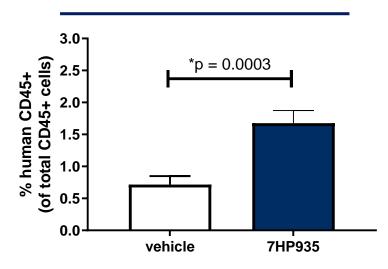


Harvest bone marrow and peripheral blood

**Bone Marrow – human CD34+** 



#### Peripheral Blood – human CD45+



## Experienced team with >5 drug approvals



#### Management



Upendra Marathi, PhD President & CEO 3 new ventures, Inventor 1 NASDAQ listing





Lionel Lewis, MB BCh, MD Chief Medical Officer Oncologist with >40 Phase I solid tumor studies

**DARTMOUTH** 



William Schary, Ph.D. VP, Clin & Reg Affairs 16 New Drugs

abbvie

#### **Board of Directors**



Joseph Bailes, MD Manager, Investor Past President,

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

**ASCO**°



Stephen A. Bent Manager, Investor Partner (ret.),





Kala Marathi, MBA Manager, Investor





**Charles Sheedy Observer, Investor** 

FAYEZ SAROFIM & co.

## The impact of CPRIT on alitegimod



### **Funds**

- CPRIT funds MD Anderson
  - ~\$0.9 million
- NIH SBIR Program funds
  - \$7 million
- CPRIT & NIH
  - 17.5 million

### **Outcomes**

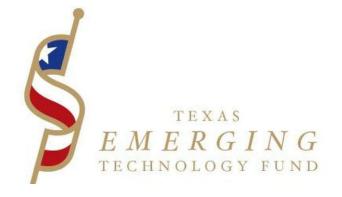
2014, Integrins are important for solid tumor immunity

2015-2022, Pre-Clinical & Phase I

2023-2026, 7HP111 Phase lb/lla

## Impact of State of Texas Economic Funds







\$2 Million in 2007







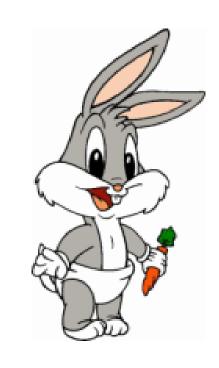
\$13.5 Million in 2023



The State of Texas Economic Funds are critical in times of economic distress

## Final thoughts





Upendra Marathi
<u>upendra@7hillspharma.com</u>
<u>www.7hillspharma.com</u>

- Integrins are essential to a productive immune response
- First-in-concept integrin agonists to expand the curative potential of immunotherapy for cancer
- CPRIT is essential

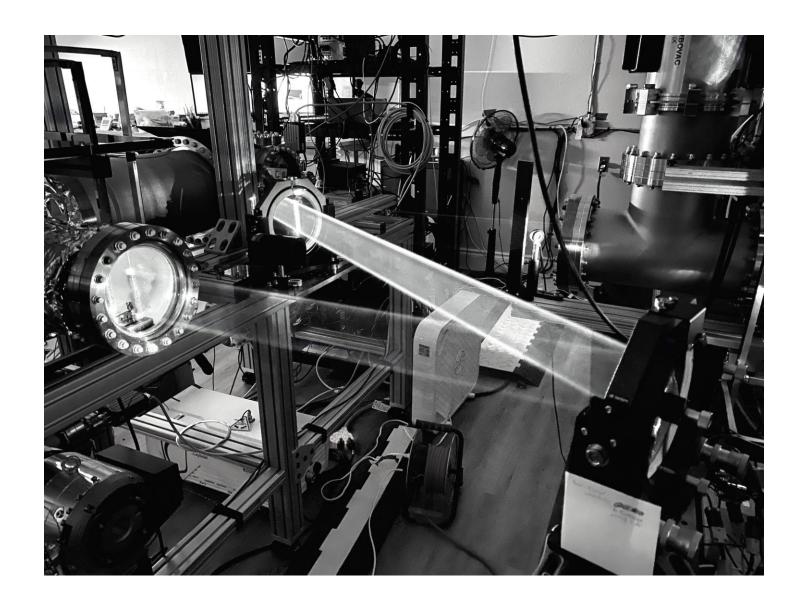


## **Enrichment of Stable Ytterbium-176 for Production of No-carrier-added Lutetium-177 for Radiotherapies**

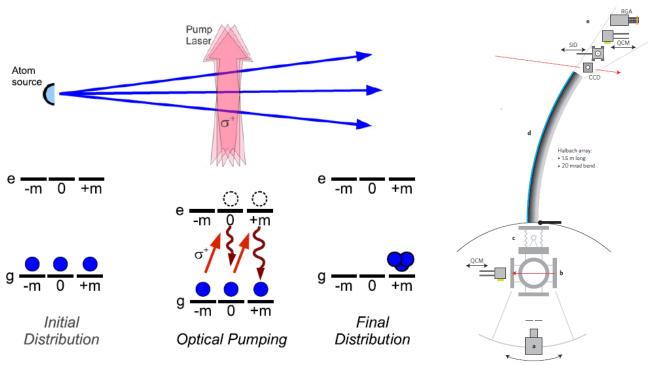


Kirk Dorius - CEO **Atom Mines** kirkdorius@atommines.com

OCTOBER 2-3, 2023 · MOODY GARDENS HOTEL AND CONVENTION CENTER · GALVESTON, TEXAS



## **MAGIS** Isotope Separation



- •MAGIS is efficient, achieving a high degree of separation with low energy input.
- •MAGIS excites selected isotopes with a tuned laser and then uses magnetic fields to separate the excited isotopes.

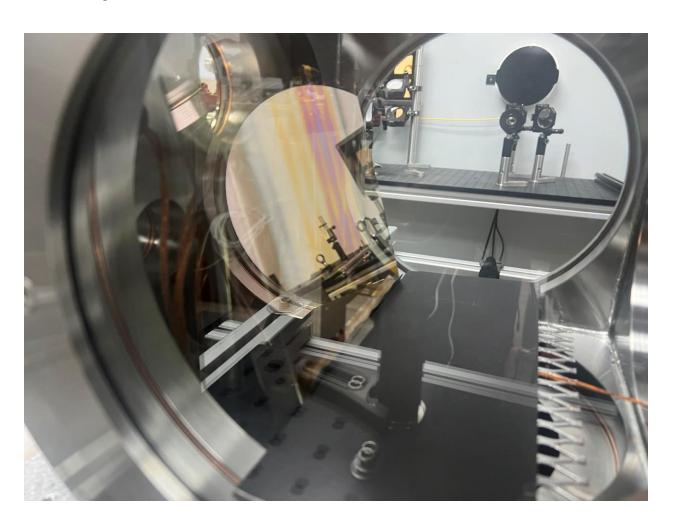
# Magnetically-Activated and Guided Isotope Separation (MAGIS)



MAGIS offers a domestic reliable supply of 176Yb and other isotopes for medicine.

(12) United States Patent Raizen et al.			(10) Patent No.: (45) Date of Patent:		US 8,672,138 B2 Mar. 18, 2014	
(54)	54) ISOTOPE SEPARATION BY MAGNETIC ACTIVATION AND SEPARATION		(56) U.S		References Cited  ATENT DOCUMENTS	
(71)	Applicant:	Board of Regents, The University of Texas System, Austin, TX (US)	848,600 A 3,953,731 A	4/1976		
(72)	Inventors:	Mark G. Raizen, Austin, TX (US); Bruce G. Klappauf, Austin, TX (US)	4,081,677 A 4,149,077 A 5,705,902 A 7,323,651 B2	4/1979 1/1998	Dawson Yamashita et al. Merritt et al. Jeong et al.	
(73)	Assignee:	Board of Regents The University of Texas System, Austin, TX (US)	2011/0278203 A1	11/2011	Raizen et al.  VT DOCUMENTS	

## Stripes of Collected Yb-176



# CPRIT Funding for Commercial Scale-up

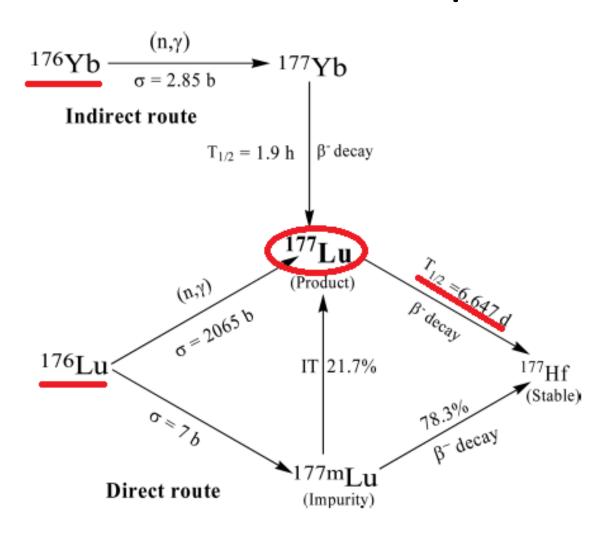


# MAGIS Can Separate Over 130 Isotopes of Over 30 Elements

	Element	Stable Isotopes
1	Li	6,7
2	Mg	24,25,26
3	Ar	36,38,40
4	К	39,40,41
5	Ca	40,42,43,44,46,48
6	Cr	50,52,53,54
7	Fe	54,56,57,58
8	Ni	58,60,61,62,64
9	Cu	63,65
10	Zn	64,66,67,68,70
11	Ga	69,70
12	Kr	78,80,82,83,84,86
13	Rb	85,87
14	St	84,86,87,88
15	Мо	92,94,95,96,97,98,100

	Element	Stable Isotopes
16	Ag	107,109
17	Cd	106,108,110,111,112,113, 114,116
18	ln	113,115
19	Xe	124,126,128,129,130,131, 132,134,136
20	Ba	130,132,134,135,136,137, 138
21	Nd	142,143,144,145,146,148, 150
22	Gd	152,154,155,156,157,158, 160
23	Dy	156,158,160,161,162,163, 164
24	Er	162,164,166,167,168,170
25	Χþ	168,170,171,172,173,174, 176
26	Hg	196,198,199,200,201,202, 204
27	Л	203,205
28	Si	
29	Sn	
30	Ge	
31	<u>P.b</u>	

## Production of Lu-177 for Cancer Beta-therapies





Kirk Dorius - CEO
Atom Mines
kirkdorius@atommines.com

### PRANA THORACIC

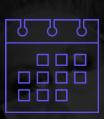
The future of early intervention in lung cancer



# BY THE NUMBERS



Lung cancer is the #1 cancer killer in the US and we don't find it early enough



More than half of patients with lung cancer die within a year of being diagnosed



New guidelines in place for 15 million Americans to be screened for lung cancer annually

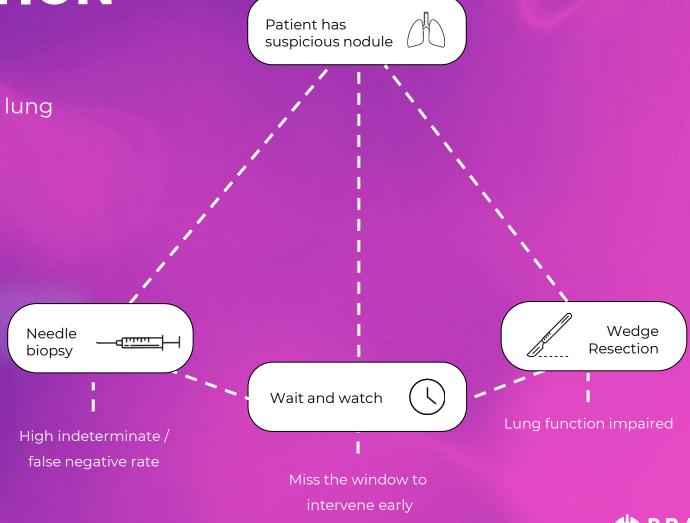


<5% of eligible patients are undergoing screening



# EARLY INTERVENTION IN LUNG CANCER

Physicians need a better tool to diagnose lung cancer early

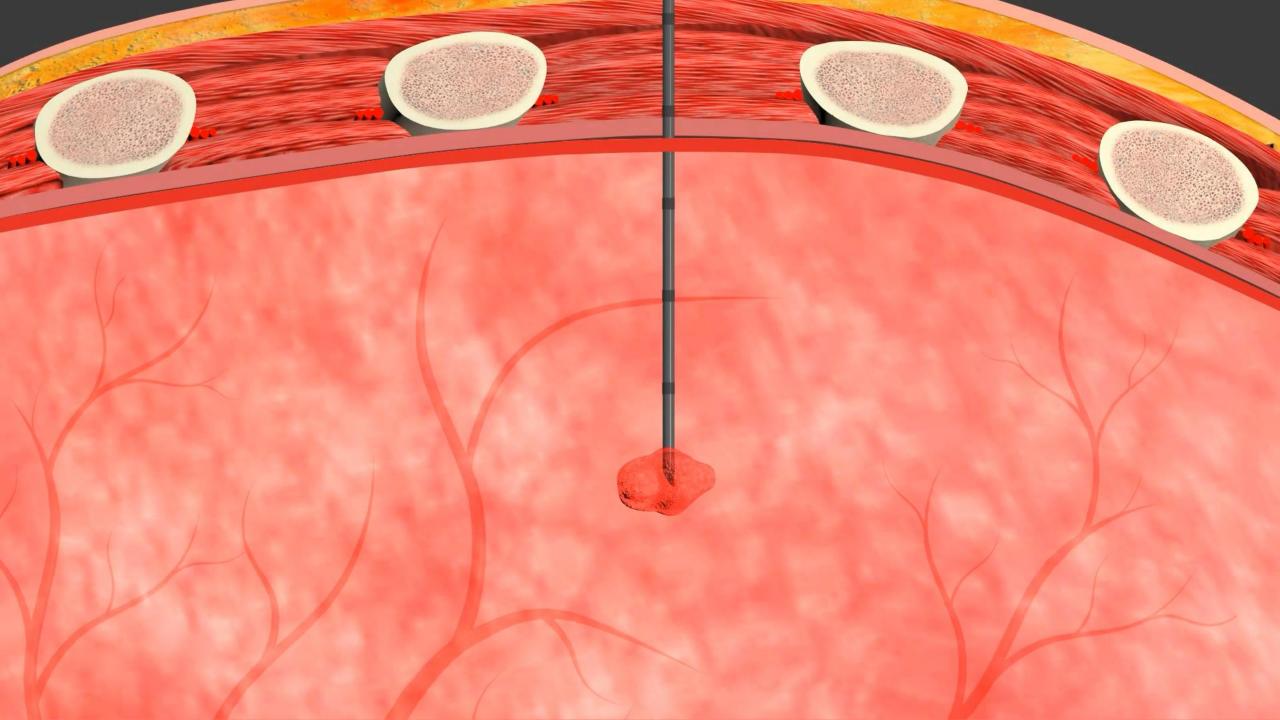




### ThoraCore

Prana Thoracic is developing an electrosurgical instrument intended for <u>cylindrical</u>, <u>single-port excision</u> of <u>targeted</u> lung tissue, using bipolar RF energy for <u>sealing</u>.

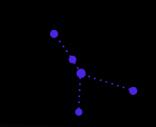




### PIPELINE & VISION



Definitive diagnosis and molecular testing of lung abnormalities



Treatment of pulmonary metastases



Treatment of earlystage primary lung cancer in combination with ablation / drug delivery



Applications in other solid organs: breast, liver, kidney, lymph nodes.



### **Traction**

#### Executive:

0

- Full Time Team of 6 Hired
- Series A Closing of \$3M; CPRIT Grant of \$3M
- 2 New SAB Member

02

#### **Product Development:**

- Completed and Tested "Alpha" Prototype
- Invention of Lung Stabilization Port for Transition to IR Suite
- 3 Additional Animal Studies Completed

03

#### Clinical / Regulatory:

- FDA Pre-Sub Meeting Confirmed *De Novo* Pathway
- Innovation Award at Society Meeting (ISMICS 2023)
- FIH + Pivotal Study Synopses Complete

#### Quality:

04

- Phase II Design Review Complete
- QMS and QMS Training Implemented (100% Complete)
- Quality Management Review Held





### **Meet Our Team**



Joanna Nathan
Chief Executive Officer
New Ventures at J&J CDI
Venture Fellow at Mercury Fund
Director of Product Development
at Saranas



Chief Operating Officer
25 years leading first to market
innovation in regulated manufacturing
environments. Executive at various
medtech startups, Medtronic, Guidant,

Ken Bueche

and Ethyl



Chief Medical Officer

20 years clinical practice as a thoracic surgeon @ Cedars Sinai, St Joseph's and Hoag Hospital Ran multidisciplinary tumor boards at these hospitals

Rick Fischel, MD



Ed Boyle, MD
Chief Scientific Officer
Founding CEO of ClearFlow
Founder of MDI Partners
Founder of Elixis (acquired by DCCA)
20 years clinical practice as a thoracic surgeon



Lance Black, MD
Chief Clinical Strategy Officer
20 years in healthcare

20 years in healthcare
Family medicine physician for USAF
Founder and CMO at XN Health
Senior Medical Director at 3ive Labs
Associate Director at TMC Innovation



Jodie Rodriguez
Sr. Director of Quality Assurance

20 years in quality assurance, including leadership roles at SkinMedica and Triliant Surgical Senior Engineer at Fujifilm Diosynth



**Carolyne Lu**Director of Clinical & Regulatory
Strategy

Product Development Engineer at Procyrion; innovation experience at J&J CDI, manufacturing process experience at Boston Scientific



Jay Salazar
Director of Product Strategy

Product Development Engineer at J&J Center for Device Innovation



**Laura Gonzalez** 

Product Development Engineer

R&D experience at J&J Center for Device Innovation



### Clinical Advisors



Mara Antonoff
MD Anderson
Thoracic Surgeon
Clinical focus on thoracic surgical oncology

**Billy Cohn** 

**Rich Miller** 



Center for Device Innovation

Executive Director of TMC Center for Device Innovation

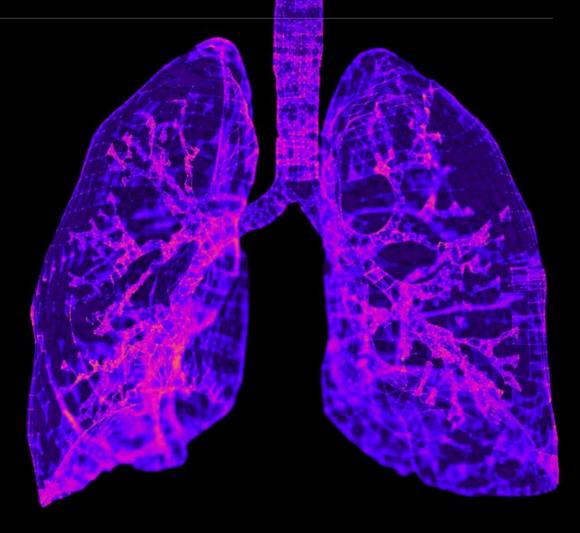
Founder of TVA, Sentreheart, Bivacor



Penrose S Francis Health

Thoracic Surgeon

Clinical focus on thoracic surgery in community setting





### **CPRIT**

CPRIT funding has enabled us to attract technology and funding from the coasts and hire homegrown top tier talent

#### **Technology**

ThoraCore was invented by thoracic surgeons on the West Coast and its early development was seeded by J&J

#### **Team**

Prana Thoracic's full-time team consists of locally developed talent with significant experience across medtech functions



### PRANA THORACIC

The future of early intervention in lung cancer





### **Transforming Immuno-Oncology (IO)**

**Presentation to:** 



OCTOBER 2-3, 2023 • MOODY GARDENS HOTEL AND CONVENTION CENTER • GALVESTON, TEXAS

Oct. 2023



This presentation ("Presentation") is for informational purposes only to assist interested parties in making their own evaluation with respect to ImmunoGenesis, Inc. ("ImmunoGenesis" or the "Company"). The information contained herein does not purport to be all-inclusive and none of the Company, its affiliates nor any of its or their control persons, officers, directors, employees or representatives makes any representation or warranty, expressed or implied, as to the accuracy, completeness or reliability of the information contained in this Presentation. You should consult your own counsel and tax and financial advisors as to legal and related matters concerning the matters described herein, and, by accepting this presentation, you confirm that you are not relying upon the information contained herein to make any decision.

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Certain statements in this presentation may be considered forward-looking statements. Forward-looking statements generally relate to future events or the Company's future financial or operating performance. In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expect," "intend," "will," "estimate," "anticipate," "believe," "predict," "potential" or "continue," or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by the Company and its management, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Factors that may cause actual results to differ materially from current expectations include, but are not limited to, various factors beyond management's control including general economic conditions and other risks, uncertainties and factors. Nothing in this presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. The Company does not undertake any duty to update these forward-looking statements.

### **2011-2014: Immunotherapy Revolutionizes the Treatment of Cancer for Millions of Patients**





James Allison wins Nobel Prize for Discovery of CTLA-4 inhibitor



YERVOY®: CTLA-4 inhibitor approved 2011



KEYTRUDA® & OPDIVO®: PD-1 inhibitors approved 2014 & 2015

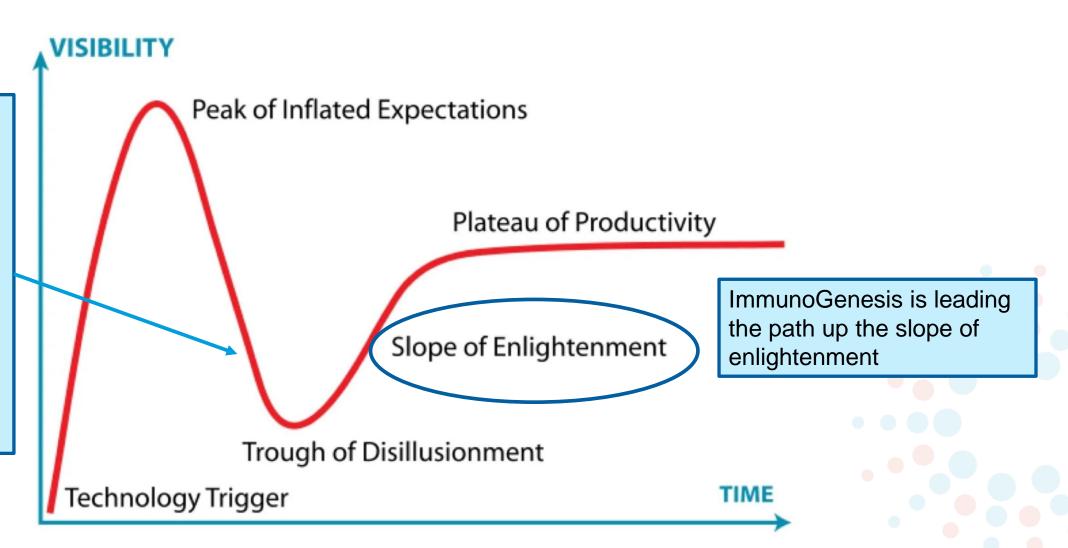




### Immuno-Oncology (IO) Development has Followed the Gartner Hype Cycle for Emerging Technologies



After initial breakthrough, a "gold rush" ensued characterized by frenzied development with little scientific rationale – this has led to IO disillusionment





#### **ImmunoGenesis Investment Thesis**

- IMGS-001 disrupts the cancer treatment landscape
  - Opportunity to more than triple sales of market leader, Keytruda (\$25B annual revenue)
  - First patient to be dosed Sept. 27
- IMGS-101(EVO) targets key immune barrier
  - \$2-5B annual revenue potential
  - First patient to be dosed in Q4 2023
- Founder is a trailblazer in immuno-oncology
- \$35M raised since founding via non-dilutive grants and convertible notes
  - Efficient use of funds (eg, \$250K monthly overhead) to ready 2 assets for clinical trials
- Series A of \$40-50M drives \$10-30B near-term exit opportunity



#### Founder: Michael A. Curran, PhD Associate Professor of Immunology, MD Anderson



#### **Trailblazer in Immuno-Oncology**

- Played pivotal role in creating the immuno-oncology industry with Nobel Laureate, James Allison
- Invented the most effective checkpoint combination
- Extensive drug development expertise
- Highly sought after for Advisory panels e.g., Pfizer, AstraZeneca, Merck;
   Pfizer tried to hire Dr. Curran multiple times to run Oncology R&D
- Curran Lab re-envisioned IO beginning in 2013
- 2019 ImmunoGenesis was born

#### **Experienced Team Driving Results**

#### **MANAGEMENT**





James A. Barlow, Jr. | CEO and President











Freddi F. O'Brien | Chief Financial Officer











Jeremy Barton, MD | Acting Chief Medical Officer









Matthew Hemberger, PhD | Senior Director, CMC & Quality







Federica Pericle, PhD | Chief Scientific Officer







Christine Gagliardi, PhD | Director, R&D







Charles Schweizer, PhD | SVP Clinical Development











Amanda Sanders | Associate Director, Clinical Operations







#### SCIENTIFIC, CLINICAL, & BUSINESS ADVISORS



Michael A. Curran, PhD Founder and SAB Head MDAnderson Cancer Center



David Hong, MD Clinical Advisor **MDAnderson** Cancer Center



**Jacques Gaudreault** Nonclinical Consultant







Robert Stein, MD PhD Member, Board of Directors







### **Current PD-1 Inhibitor Therapy Dominates IMGS-001 Resolves Major Gaps**





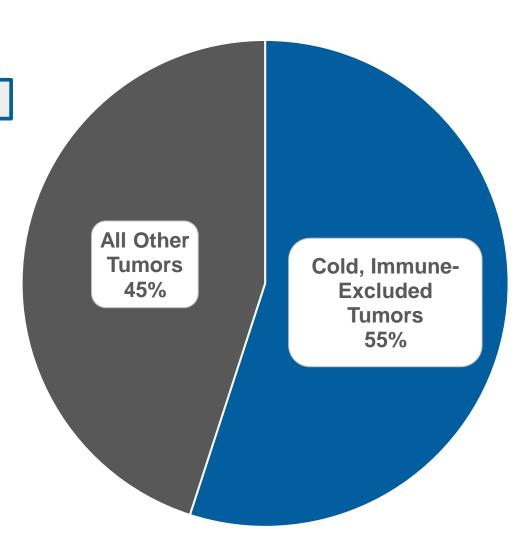
**KEYTRUDA**°











#### **IMGS-001**

Re-envision and reset the starting point for cold tumor efficacy

>\$50B market







#### **Not Enough Patients Benefit from PD-1 Inhibitors**

- Most tumors lock out T cells; current PD-1 inhibitors don't address this problem
- PD-1 inhibitors in combination with any other drugs have not solved the issue
  - Success rate: 1:287 combination trials

#### How does this translate into actual patient statistics?

- <45% of cancer patients can receive a PD-1 inhibitor; <20% of those respond</li>
  - Goal of IMGS-001 is to broaden indication to upwards of 100% of patients
  - Our models indicate that IMGS-001 can drive 4-6X the response rate of current PD-1s

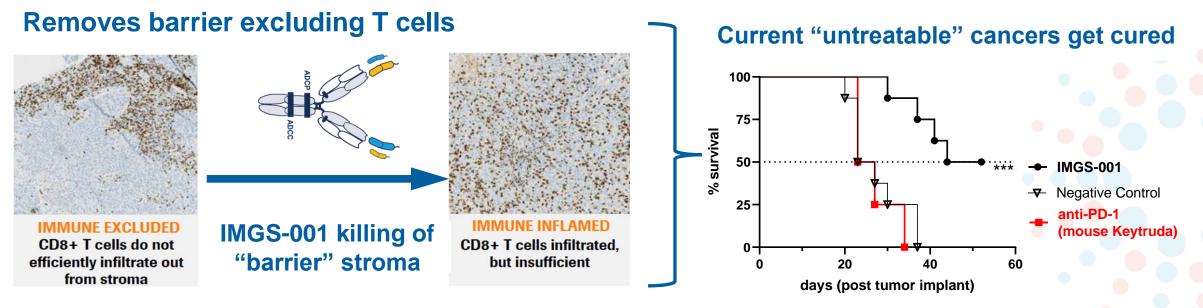
"Combinations with current PD-1 inhibitors are not effective... Your approach with IMGS-001 is exactly what is needed – a revolutionary PD-1 inhibitor therapy that has optimal blockade and enables the killing of immunosuppressive cells. This agent can transform cancer treatment."

Dr. Jedd Wolchok, Current Director Weill Cornell Cancer Center Previous 16 years Director of Immunotherapy Sloan Kettering



#### **IMGS-001 Transforms Immuno-Oncology**

- IMGS-001 engineered to optimize PD-1 blockade and address T cell lock-out
- Potential to significantly outperform Keytruda across all cancers
- Can act as the superior foundation for combination trials
- Market approval expected simultaneous to Keytruda/Opdivo loss of exclusivity





#### **CPRIT Grant Positioned IMGS to Transform IO**

- \$15.5M CPRIT grant was first significant influx of capital into company
  - Led to additional raise of \$13.3M in convertible notes as matching funds
- Independent validation of value proposition for IMGS-001
- Facilitated the creation of a world-class team
- Led to company being headquartered at JLabs TMC
- Funded manufacturing, tox and other IND-enabling activities for IMGS-001
- Company is now positioned to bring this groundbreaking treatment to patients and completely disrupt the cancer treatment landscape









# Coming up next: Reception, Gala Dinner, and Awards Ceremony Francis Moody Foyer & Ballroom

### Share the Experience

Tag us on any post from or about the Innovations VI conference. @CPRITTEXAS

Like and Share our posts about the conference and our grantees and grantee institutions or organizations

Include one of our conference hashtags listed below:

#CPRITInnovations #TexasCancerConference #TexansConquerCancer

