



# Harnessing the Immune System to Improve Human Health

Corporate Deck

# Inimmune

**Our Focus:** Discovery & development of disease modifying immunotherapies

**Our Science:** Novel compounds designed to target relevant pathways of the innate immune system and drive a therapeutic response

## Clinical Applications:

### Allergy

Disease-modifying therapy to stop allergy symptoms before they begin

### Oncology

Activating a patient's immune response to fight cancer

### Vaccine Adjuvants

Developing new classes of vaccine adjuvants to treat a broad range of diseases and conditions

### Infectious Diseases

Enhancing vaccine responses through precise immune stimulation

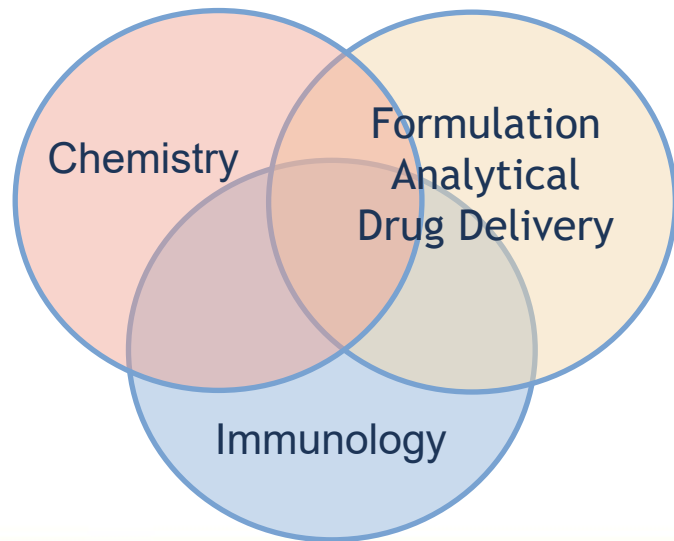
### Autoimmune Diseases

Preventing the progression of autoimmune diseases by interrupting the root cause of immune system malfunction



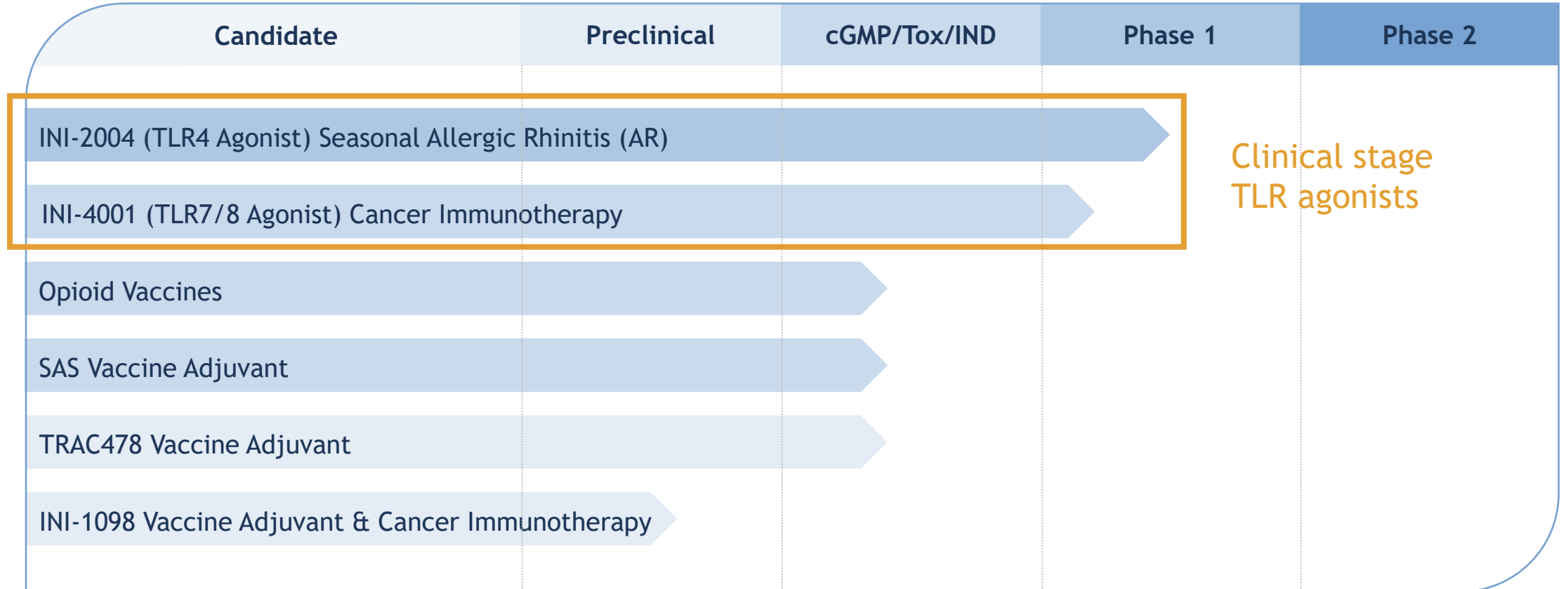
# The Inimmune Difference: Global leaders in innate immune modulator development

- Company formed in 2016 by former GSK Adjuvant Discovery and Development Team
- Over 20 years of experience in immuno-modulatory drug discovery and development
- Strong external funding and IP generation >\$150 M in NIH Contracts and 20 patents in the past 10 years
- Expertise from discovery through clinical implementation



- Synthetic molecule design and synthesis
- Formulation and analytical chemistry
- Preclinical vaccine models, MOA, efficacy, tox
- Candidate selection, process development, scale-up, analytics, and regulatory QA/QC

# Deep Immunotherapy Pipeline



# Changing the Landscape of Immunotherapy: Allergy

## The Challenges:

- Symptomatic treatments: anti-histamines and intranasal corticosteroids
- Only disease-modifying therapy is allergen-specific immunotherapy (AIT):
  - Long-term treatment (3 to 5 years)
  - Low patient adherence and high patient costs
- Years after the approval of intranasal steroids and AIT, no significant increase in patient quality of life has been achieved<sup>1</sup>

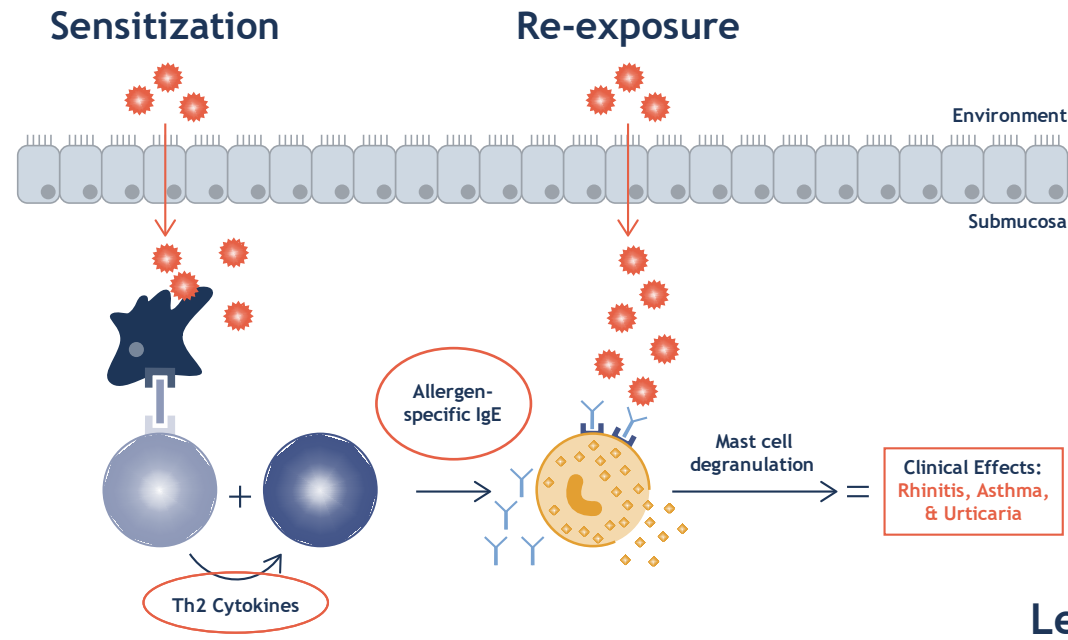
## The Solution: INI-2004

- INI-2004 is a disease-modifying therapy for allergies with the potential to be curative
- Intranasal INI-2004 Phase I trial in progress for treatment of allergic rhinitis
- Numerous follow-on indications such as food allergies, rapid protection against upper respiratory tract infections, and oncology

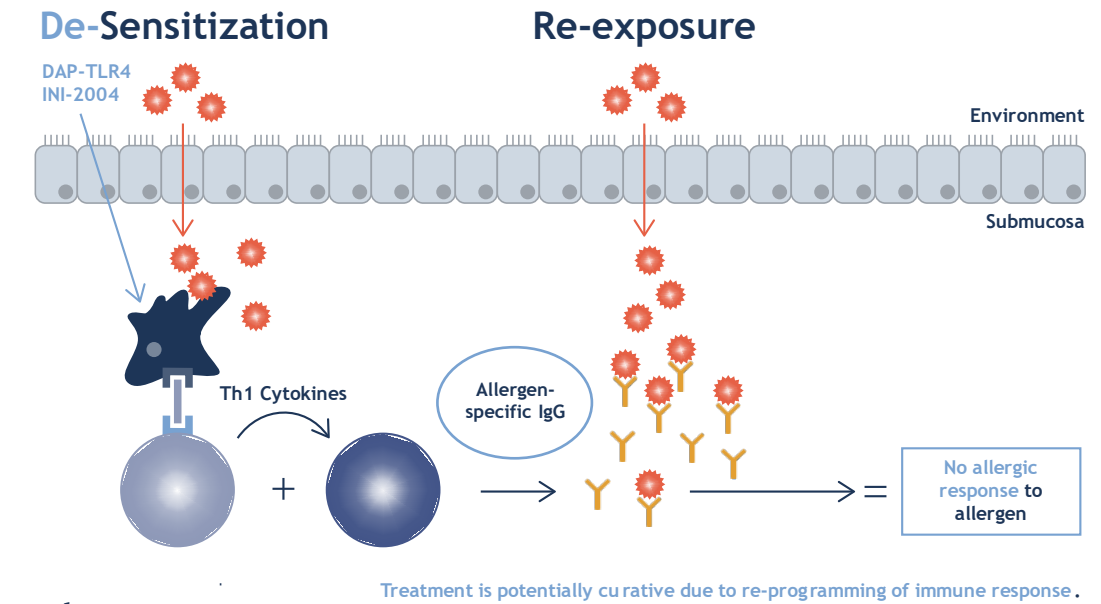
<sup>1</sup>DelveInsight, Allergic Rhinitis (AR), Market insight, epidemiology, and market forecast - 2032; Year 2023

# INI-2004 is potentially curative due to re-programming the immune response

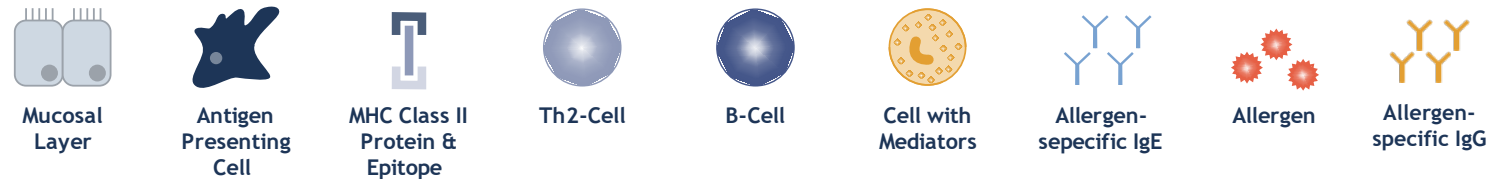
## Typical Allergic Response to Allergen



## INI-2004 Redirects Response to Allergen

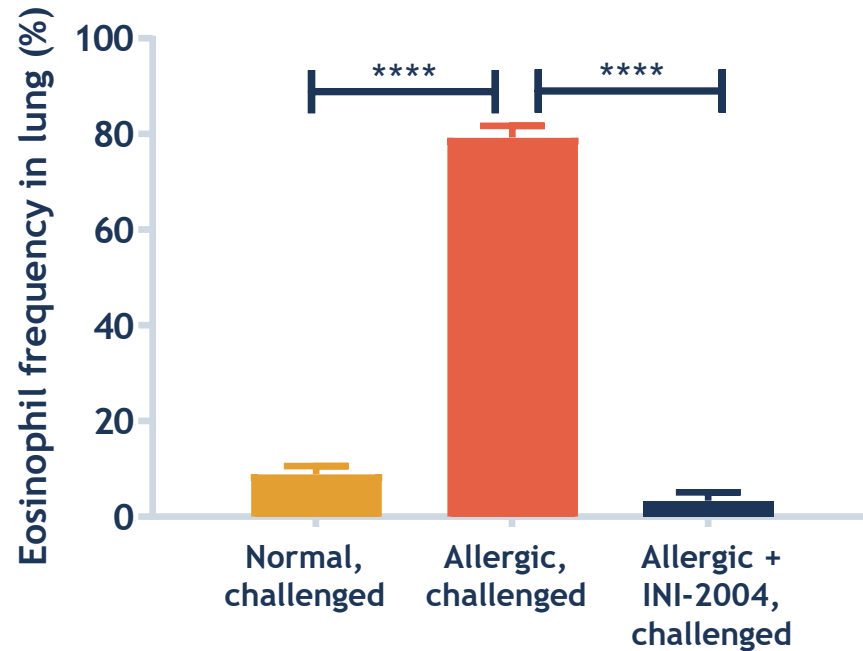


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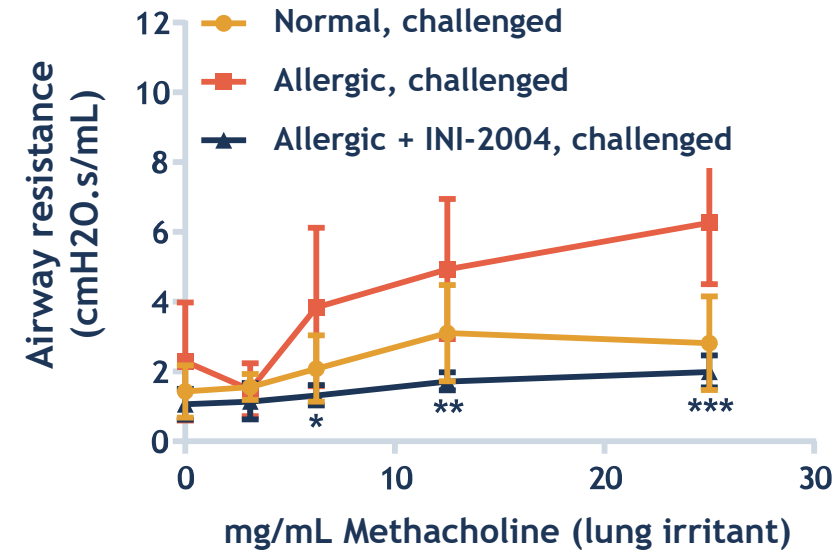


Miller, S.M., Buhl, C., Whitacre, M., Ward, J., Jackson, K., Khalaf, J.K., Bazin, H.G. and Evans, J.T., 2022. *The Journal of Immunology*, 208(1\_Supplement), pp.123-09.

# INI-2004: Reduces key measures of allergy in a mouse model



- No eosinophil infiltration after allergen challenge in allergic mice treated with INI-2004
- Eosinophils are innate immune cells that drive allergy symptoms



- Lung airway resistance reduced to normal levels in mice treated with INI-2004
- Methacholine-induced lung irritation is significantly reduced by INI-2004 treatment

Miller, S.M., Buhl, C., Whitacre, M., Ward, J., Jackson, K., Khalaf, J.K., Bazin, H.G. and Evans, J.T., 2022. *The Journal of Immunology*, 208(1\_Supplement), pp.123-09.

# INI-2004: Phase I clinical trial for AR

Single Ascending Dose (SAD) Study: Dosing complete

Multiple Ascending Dose (MAD) Study: Enrolling patients

## Phase 1 Results: SAD

- SAD study complete
- 4 dose cohorts of healthy volunteers, up to 500 µg INI-2004 administered IN
- **INI-2004 well tolerated - no drug related serious adverse events**



## Phase 1: MAD

- Four weekly doses of INI-2004 given to subjects with confirmed ragweed allergy
  - 3 dose cohorts
  - 3 ragweed challenges with symptom measurement for initial efficacy measurements
- Cohort 1 enrolled and received initial dose
- Screening and enrollment continues for cohorts 2 and 3



# Changing the Landscape of Immunotherapy: Cancer

## The Challenges:

- Recent therapeutic breakthroughs, such as Checkpoint Inhibitors (CPI), only benefit a small minority of patients
- Best-case estimates ~43% of patients eligible for CPI therapy only ~12.5% of patients helped by these drugs<sup>2</sup>

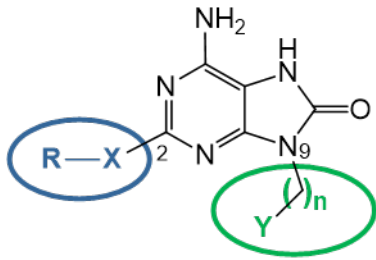
## The Solution: INI-4001

- Pre-clinical mouse models demonstrate the efficacy of INI-4001
  - INI-4001 monotherapy cures 83% in LLC
  - Synergy with anti-PD-1 and increased cure rate (70-100%) in MC38 and B16F10
- Upcoming Phase 1 clinical trial
  - Open label, all solid tumors
  - Safety and efficacy of INI-4001 alone and in combination with CPI

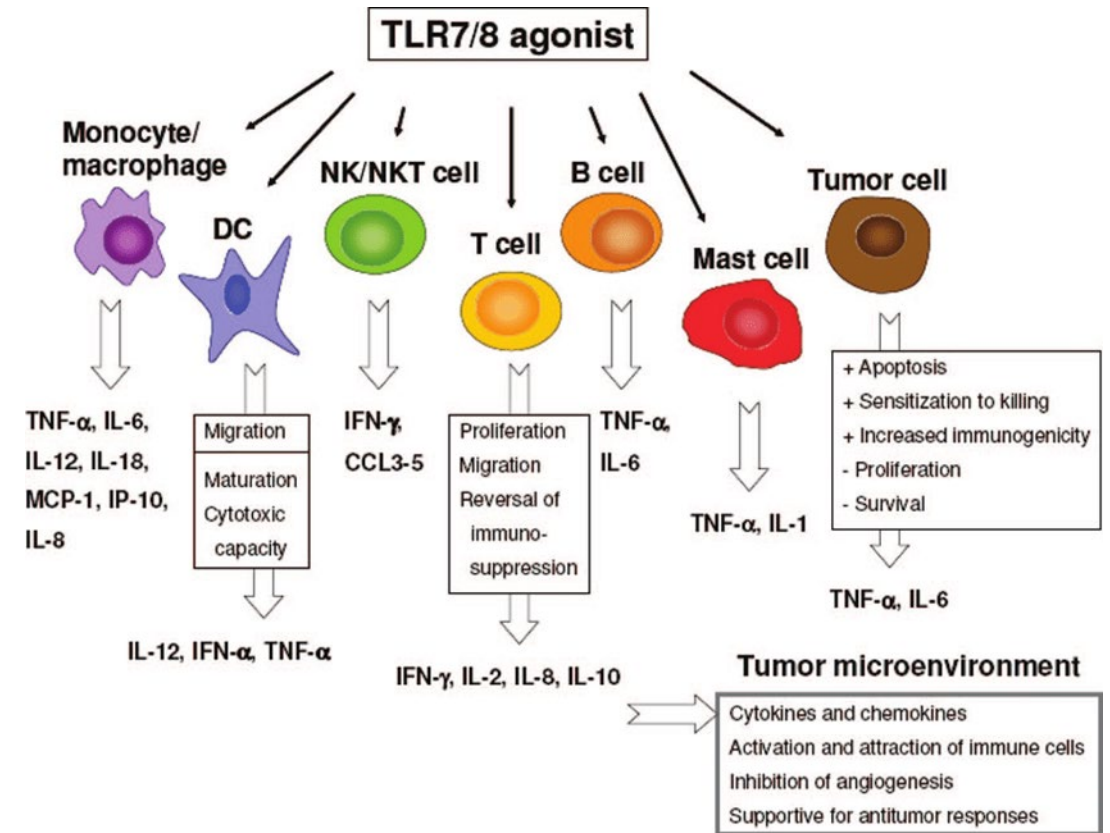
<sup>2</sup>Vision Research Reports, Cancer Immunotherapy Market, Global Industry Analysis, Size, Share, Growth, Trends, Revenue, Regional Outlook 2021-2030

# INI-4001 activates the innate immune system via TLR7/8 against cancer

## The Solution: INI-4001



- Balanced TLR7 and TLR8 immunity profile
- Nanoparticle formulation enhances anti-tumor activity, maintaining high IFN $\alpha$  production while reducing pro-inflammatory TNF $\alpha$
- Effective alone and in combination with anti-PD-1

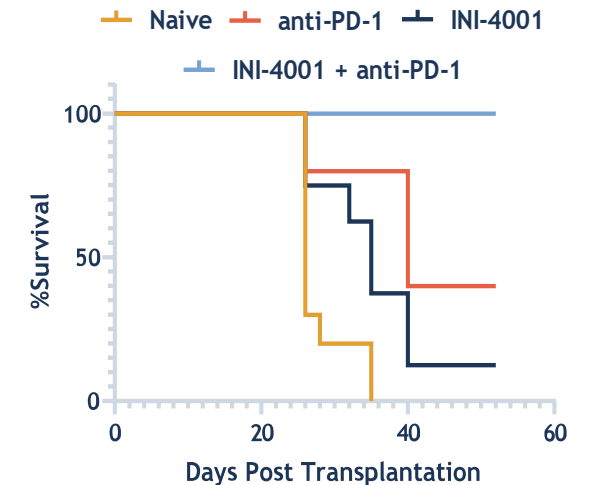
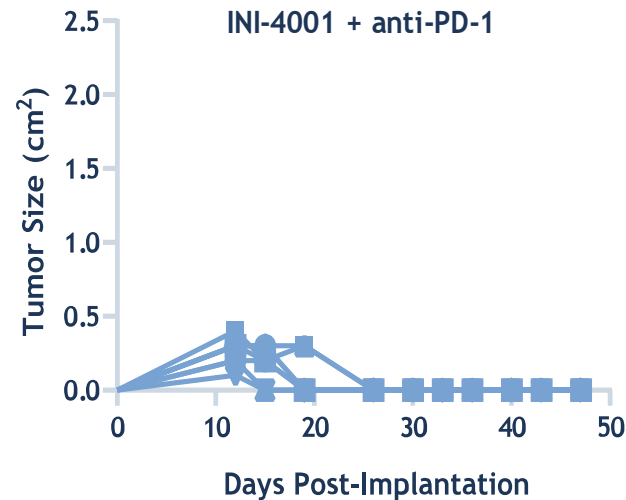
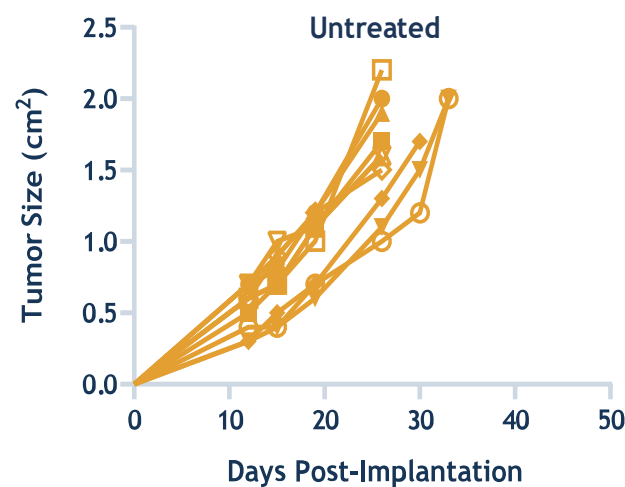


Miller, S., Beyer, C., Talbot, D., Jackson, K., Whitacre, M., Ward, J., Schoener, R., Bazin, H. and Burkhart, D., 2022, *Journal for the Immunotherapy of Cancer* Vol. 10, pp. A1211-A1211

# Expanding CPI Efficacy in Combination with INI-4001

## MC38 Tumor Model: Mouse colon cancer

Using a combination of INI-4001 + anti-PD-1, all mice were cured of MC38 tumors.



Similar results found in immunologically cold tumor model B16F10, a mouse melanoma cancer model

Miller, S., Beyer, C., Talbot, D., Jackson, K., Whitacre, M., Ward, J., Schoener, R., Bazin, H. and Burkhart, D., 2022, *Journal for the Immunotherapy of Cancer* Vol. 10, pp. A1211-A1211

# INI-4001: Upcoming Phase 1 Overview

Dose Escalation and Dose Expansion Study: INI-4001 in patients with advanced solid tumors

## Step 1: Dose escalation, INI-4001 monotherapy

- INI-4001, IV, once a week for 9 weeks
- Primary endpoint: safety and tolerability of INI-4001
- Secondary endpoints: efficacy and biomarker identification and analysis
- First patient in (FPI) January 2024



## Step 2: Combination INI-4001 and CPI

- Combination INI-4001 and approved CPI for patients that progress on INI-4001 or achieve stable disease
- Primary endpoint: safety and tolerability of INI-4001
- Secondary endpoints: efficacy and biomarker identification and analysis



# Opportunity: Seeking \$60M Series B

We are actively seeking a **lead series B investor** who shares our vision to develop new, safe, and effective immunotherapies for the treatment and prevention of cancers, allergies, infectious and autoimmune diseases.

## Advancing Opportunities

**A full \$60M series B would allow us to:**

- Complete Phase 1 INI-4001 cancer clinical trial
- Conduct Phase 2 INI-2004 allergy clinical trial
- Advance SAS adjuvant into Phase I clinical trial
- Advance lead pre-clinical research programs in oncology and autoimmune disorders to IND
- Continue funding general overhead costs through 2025



## Propelling Potential

**After Phase 2 Clinical Trials (late 2025):**

- Corporate partnership and licensing agreement(s)
- IPO or series C
- Merger and acquisition exit

# Partnerships & Collaborations

Our partnerships with top universities and biotech companies drives innovative technology and has lead to over \$150M in NIH funding



# Executive Team: Experienced Biotech & Industry Veterans



**Alan Joslyn, Ph.D.,**  
Chief Executive Officer, &  
BOD Member



**David Burkhart, Ph.D.,**  
Chief Operating Officer,  
Cofounder, & BOD Member



**Jay Evans, Ph.D.,**  
Chief Scientific and Strategy  
Officer, Cofounder, & BOD  
Member



**Mike Sullivan, CPA.,**  
Chief Financial Officer



**Jon Ruckle, M.D.,**  
Chief Medical Officer



**Helene Bazin-Lee, Ph.D.,**  
VP, Discovery, Cofounder, &  
BOD Member



**Kendal Ryter, Ph.D.,**  
VP, Manufacturing &  
Development, Cofounder



**Lucy Tennant, M.S.,**  
VP, Clinical Operations



**Michael Conger, J.D.,**  
VP, Legal & Business Strategy



# Scientific Advisory Board



**James Allison, Ph.D.**  
Chair & Professor,  
Department of Immunology,  
MD Anderson Cancer Center

2018 Nobel Prize in  
Physiology or Medicine for  
the discovery of cancer  
therapy by inhibition of  
negative immune regulation



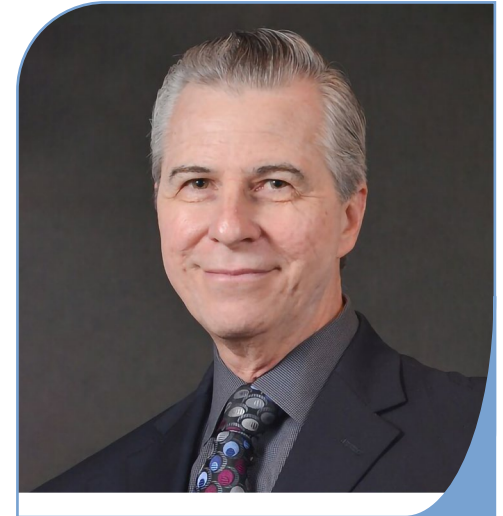
**Padmanee  
Sharma, M.D., Ph.D.**  
Scientific Director,  
Immunotherapy Platform &  
Professor of Genitourinary  
Medical Oncology &  
Immunology, MD Anderson  
Cancer Center

Internationally renowned  
expert in CPI clinical trials



**Jean-Paul Prieels, Ph.D.**  
Director: Ncardia, Nouscom,  
Leukocare, Bone  
Therapeutics, PDC\*Line  
Pharma, and Quantoom  
Biosciences

Former Senior VP of R&D at  
GSK Biologicals



**Thomas Casale, M.D.**  
Professor of Medicine &  
Pediatrics, USF

Chief of Clinical &  
Translational Research,  
Division of Allergy and  
Immunology

Former President, AAAAI





# Contact Us

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