



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

Inimmune: Recent Milestones

Allergy

Completed Phase 1 clinical studies in allergic rhinitis patients

- Intranasal INI-2004, Inimmune's novel synthetic TLR4 agonist, was well tolerated with no drug-related serious adverse events
- Dose-responsive improvements in a measure of nasal congestion compared to placebo were observed in subjects who received INI-2004

Oncology

Phase 1 clinical study with INI-4001, Inimmune's novel synthetic TLR7/8 agonist, ongoing with 3 clinical sites currently enrolling patients in Australia

Vaccine Adjuvants

Worldwide commercialization and distribution partnership with SPI Pharma for Inimmune's proprietary AS01-like and AS04-like adjuvant systems

- Both systems include Inimmune's novel synthetic TLR4 agonist INI-2002
- Manufacture of cGMP INI-2002 is complete
- AS01-like and AS04-like adjuvant system cGMP manufacture ongoing and will be available for use in toxicology (Q4 2024) and clinical studies (early 2025)

Opportunity: Seeking \$20M Series A Expansion Financing

We are actively seeking investors who share our vision to develop new, safe, and effective immunotherapies for the treatment and prevention of cancers, allergies, infectious and autoimmune diseases.

Advancing Opportunities

A \$20M series A expansion would allow us to:

- Complete Phase 1a/b INI-4001 cancer clinical trial, including monotherapy dose escalation (data expected Q1 2025) and combination with checkpoint inhibitors (data expected Q4 2025)
- Conduct Phase 2 INI-2004 allergy chamber clinical trial in allergic rhinitis with data expected Q2 2025
- Continue funding general overhead costs through 2025



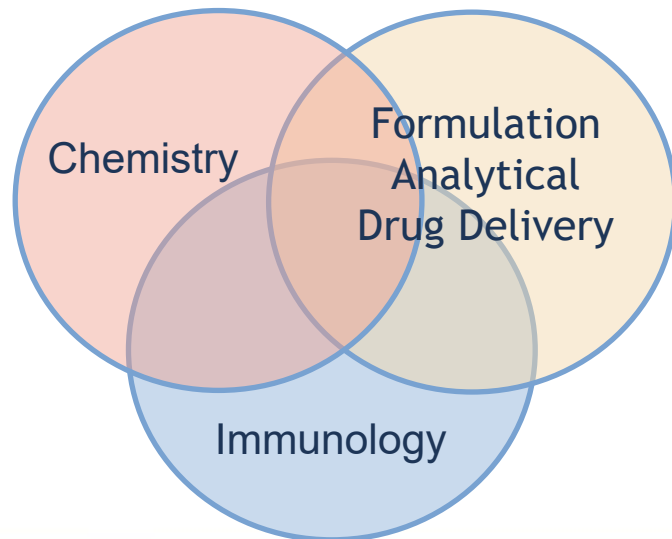
Propelling Potential

By late 2025 and advancement of clinical programs:

- Corporate partnership and licensing agreement(s)
- IPO or Series B depending on market conditions
- Merger and/or acquisition exit

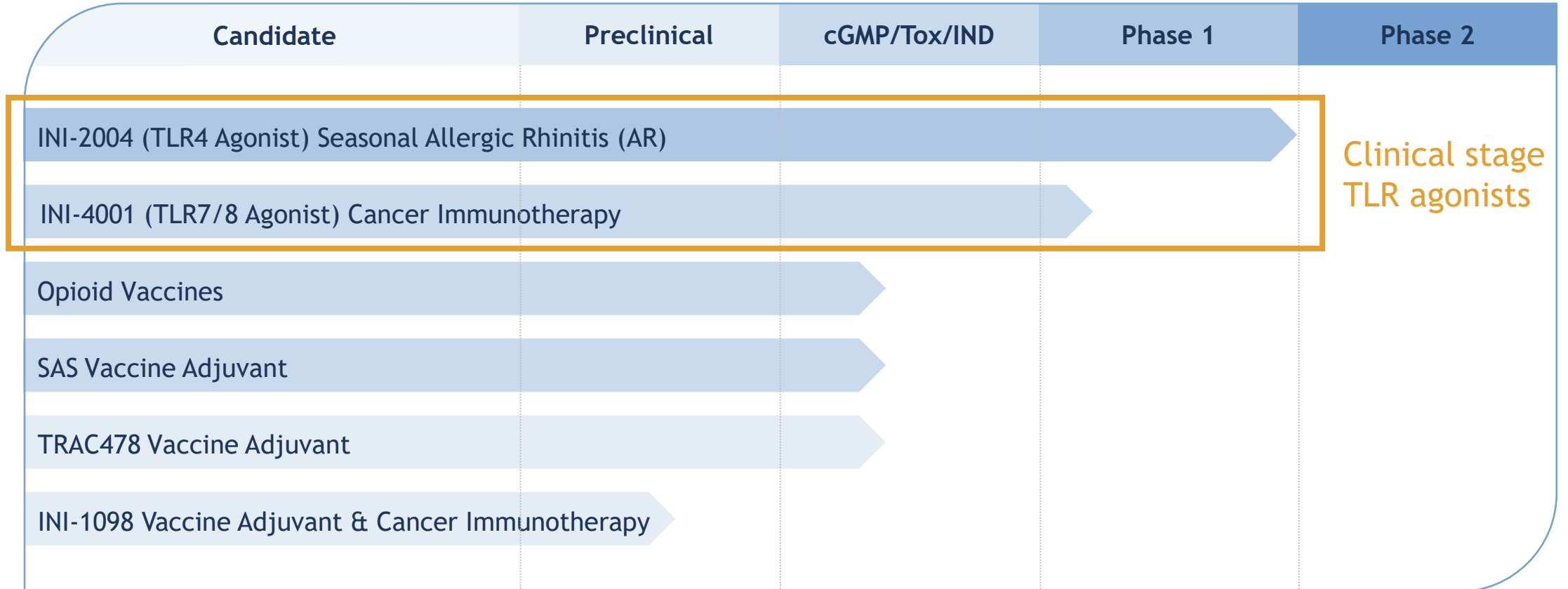
The Inimmune Difference: Global leaders in innate immune modulator development

- 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



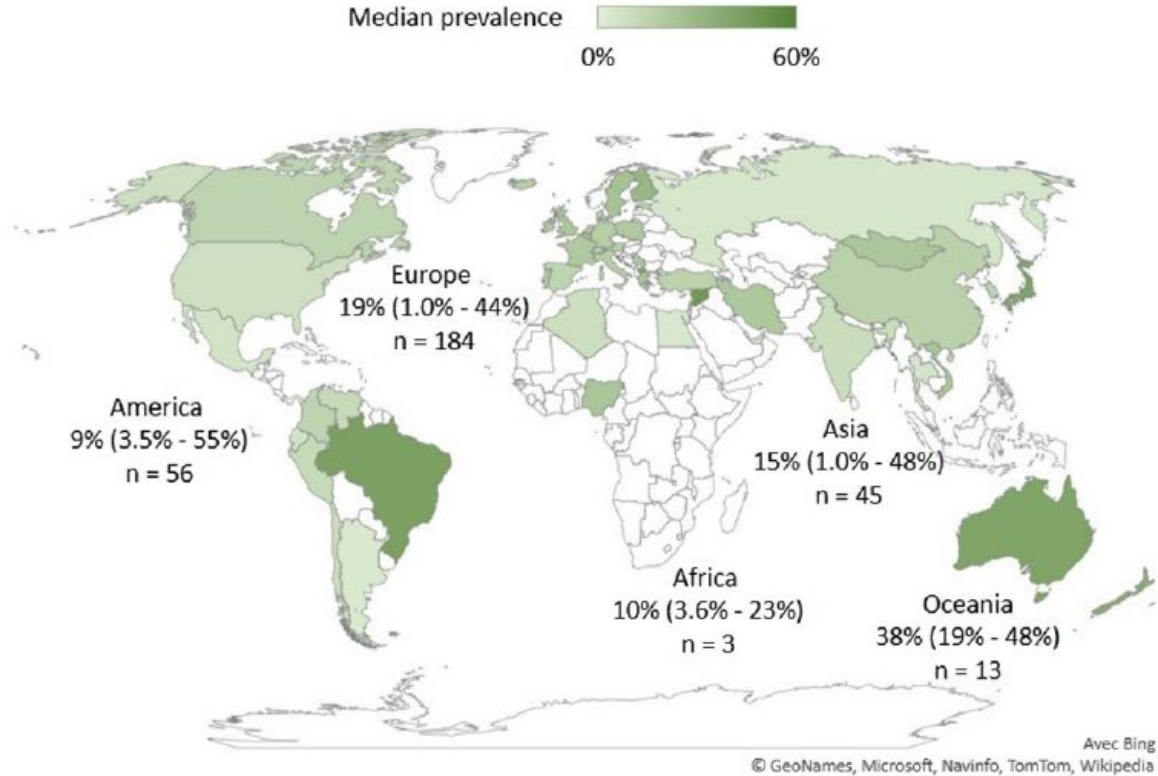
- Synthetic molecule design and synthesis
- Formulation and analytical chemistry
- Preclinical vaccine models, MOA, efficacy, tox
- Candidate selection, process development, scale-up, analytics, and regulatory QA/QC

Deep Immunotherapy Pipeline



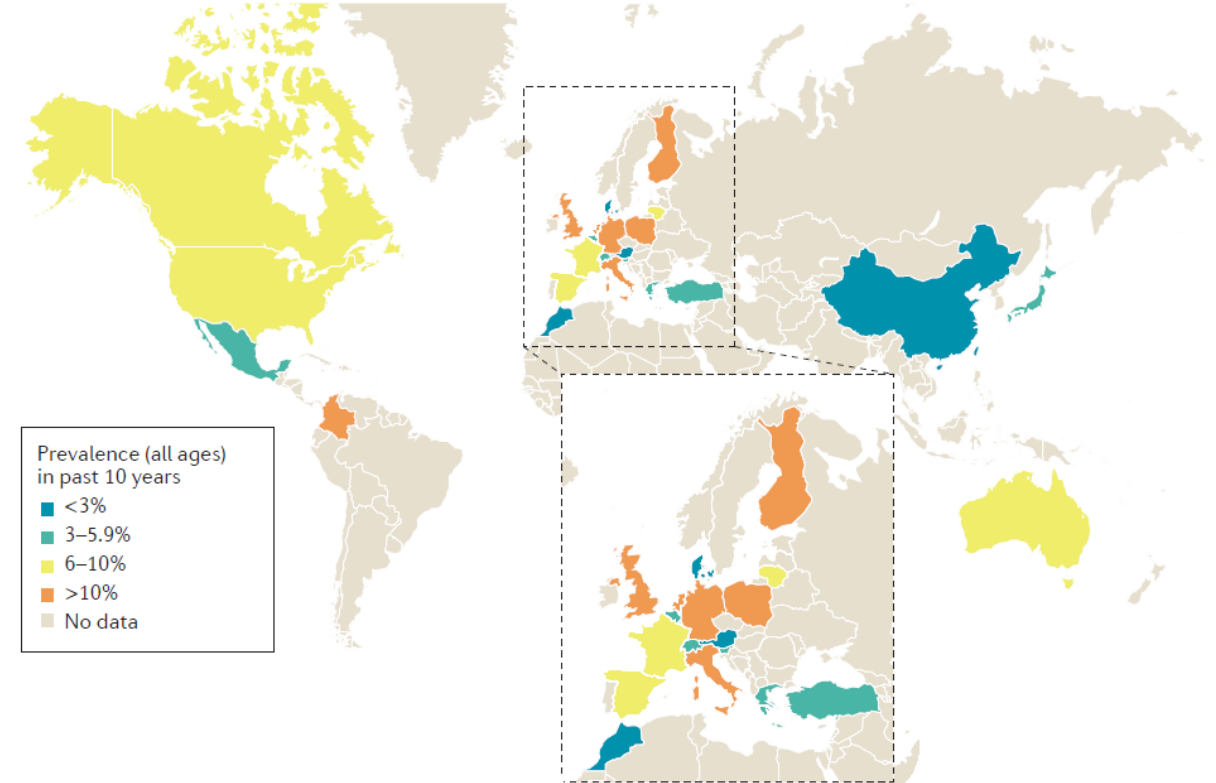
Epidemiology of Allergy

Allergic Rhinitis Prevalence



Savouré, Marine, et al. Clinical and translational allergy 12.3 (2022): e12130.

Food Allergy Prevalence



Renz, Harald, et al. Nature reviews Disease primers 4.1 (2018): 1-20.

In the US, nearly 1 in 3 adults and more than 1 in 4 children report having a seasonal allergy, eczema, or food allergy^{1,2}
Worldwide, an estimated **220 million people** are affected by food allergies

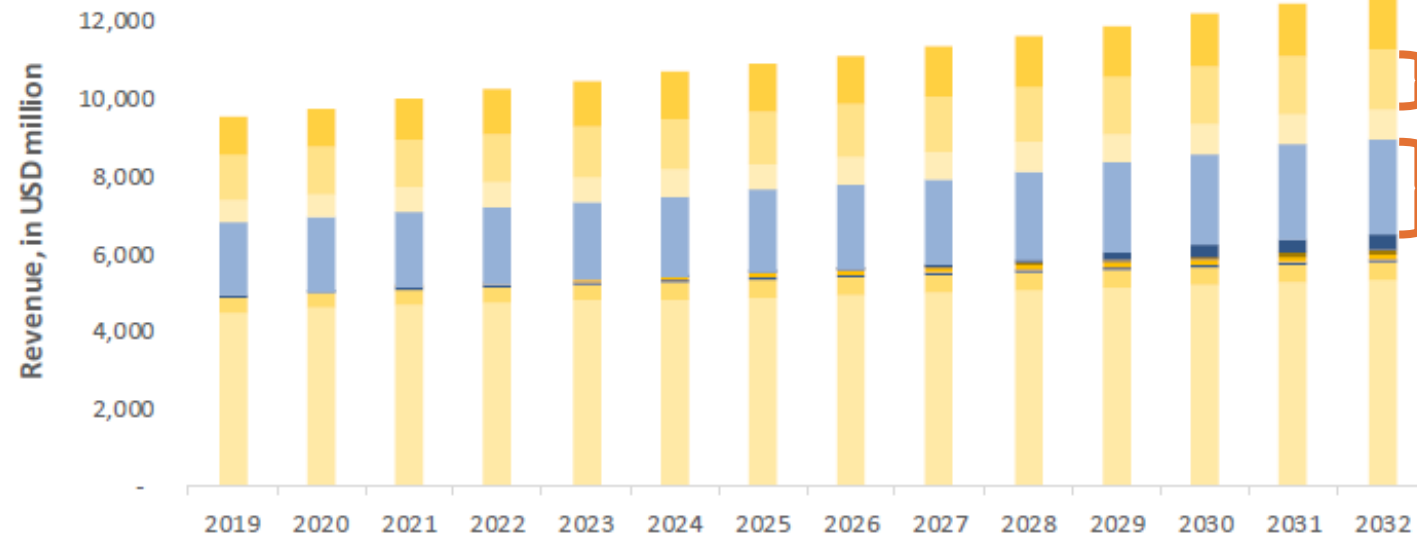
¹Ng AE, Boersma P. Diagnosed allergic conditions in adults: United States, 2021. NCHS Data Brief, no 460. Hyattsville, MD: National Center for Health Statistics.

²Zablotsky B, Black LI, Akinbami LJ. Diagnosed allergic conditions in children aged 0-17 years: United States, 2021. NCHS Data Brief, no 459. Hyattsville, MD: National Center for Health Statistics. 2023.

Allergic Rhinitis: \$10B Market with Unmet Medical Need

INI-2004: Projecting **\$1.2B revenue** by Y2

- Shortened time to efficacy compared to AIT
- Same easy IN administration as IN steroids with improved efficacy and durability of response



AIT: \$1.3B market, high cost & poor compliance
 INI-2004: >50% penetration expected by Y2

IN steroids: \$2.3B market, ~10-20% efficacy⁴
 INI-2004: >25% penetration expected by Y2

- Antihistamines
- Ryaltis
- Intranasal Corticosteroids
- Immunotherapy
- Decongestants
- Grass MATA MPL
- Mast cell stabilizers
- Xolair (Omalizumab)
- REGN5713-5714-5715
- Leukotriene receptor antagonists

Adapted from: DelveInsight, Allergic Rhinitis (AR), Market insight, epidemiology, and market forecast - 2032; Year 2023

⁴Carr, Warner, et al. Journal of Allergy and Clinical Immunology 129.5 (2012): 1282-1289.

INI-2004: Disease modifying immunotherapy for allergy

Current allergen-specific immunotherapies

- Only approved disease-modifying therapy for rhinitis is allergen-specific immunotherapy (AIT):
 - Requires weekly injections for 20-25 weeks followed by bi-monthly injections for 2-5 years
 - Low compliance and high costs \$1000 - 6000 per treatment course
- Years after approval of IN steroids and AIT, no significant increase in patient quality of life has been achieved³
- Only approved food allergy treatment: PALFORZIA for peanut allergy, oral immunotherapy (OIT)
 - FDA and EC approved; limited treatment adoption by patients and physicians due to AEs and complicated dosing

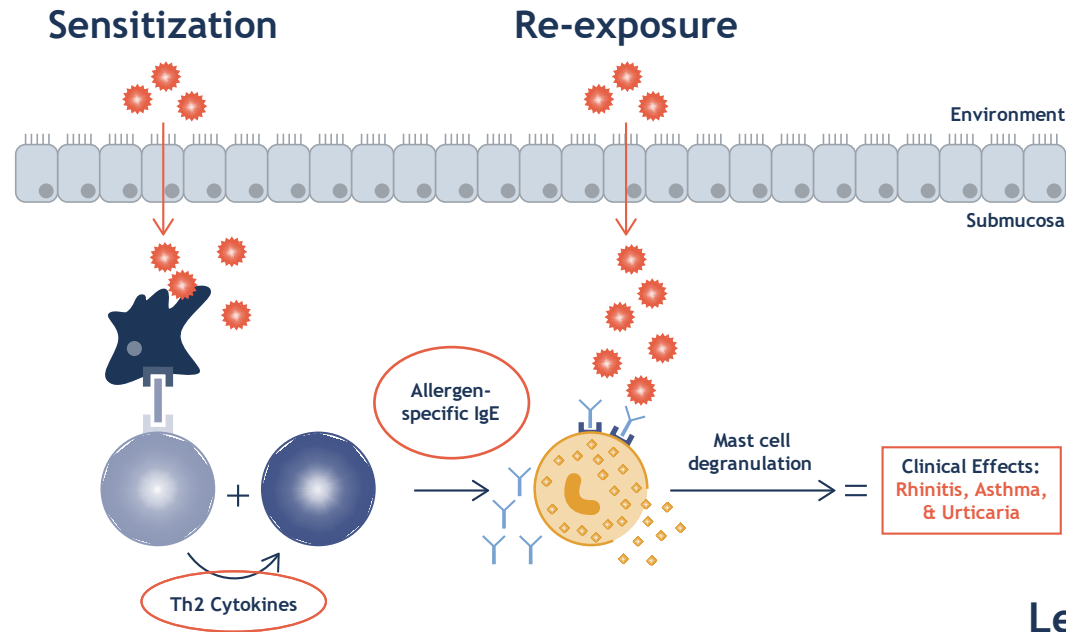
INI-2004: allergen agnostic immunotherapy

- Disease-modifying, allergen-agnostic therapy for airborne and food allergies that may be curative
- Needle-free delivery: intranasal (IN) for airborne allergens, oral mucosal for food allergy
- Rapid onset of action and shortened treatment course compared to AIT
- Increased patient compliance compared to AIT due to IN delivery and time to efficacy
- Numerous follow-on indications, e.g. rapid protection against upper respiratory tract infections, oncology immunotherapy

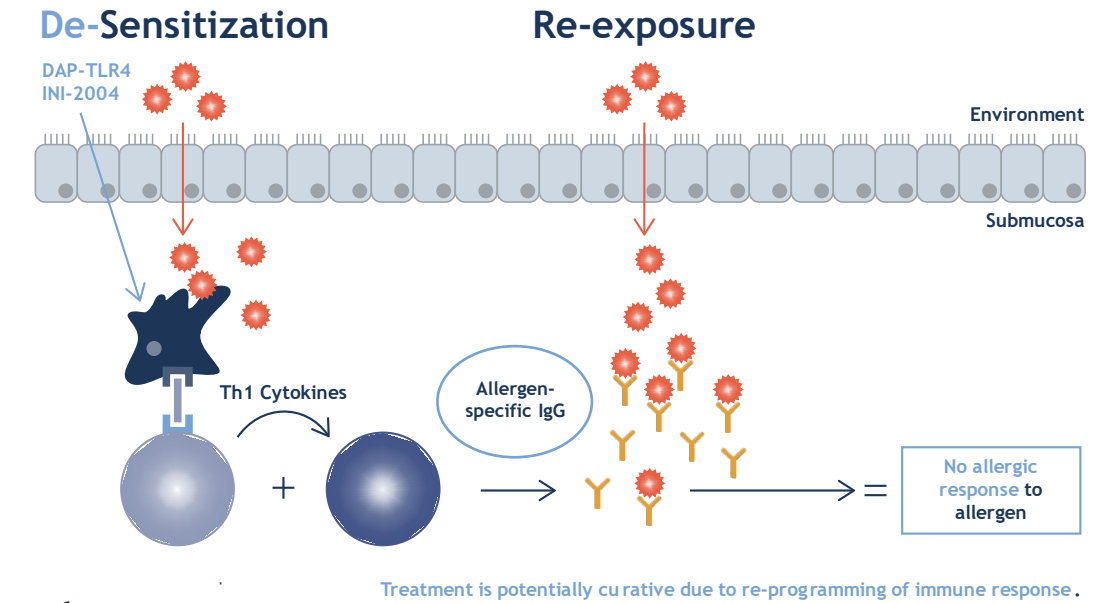
³DelveInsight, Allergic Rhinitis (AR), Market insight, epidemiology, and market forecast - 2032; Year 2023

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

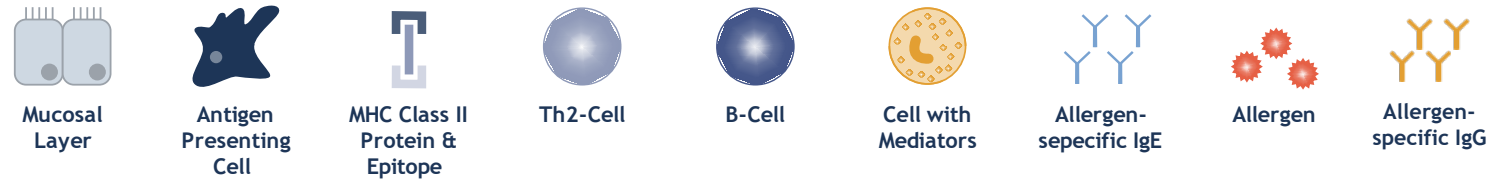
Typical Allergic Response to Allergen



INI-2004 Redirects Response to Allergen



Legend



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: **Complete**

Multiple Ascending Dose (MAD) Study: **Complete**

Phase 1 Results: SAD

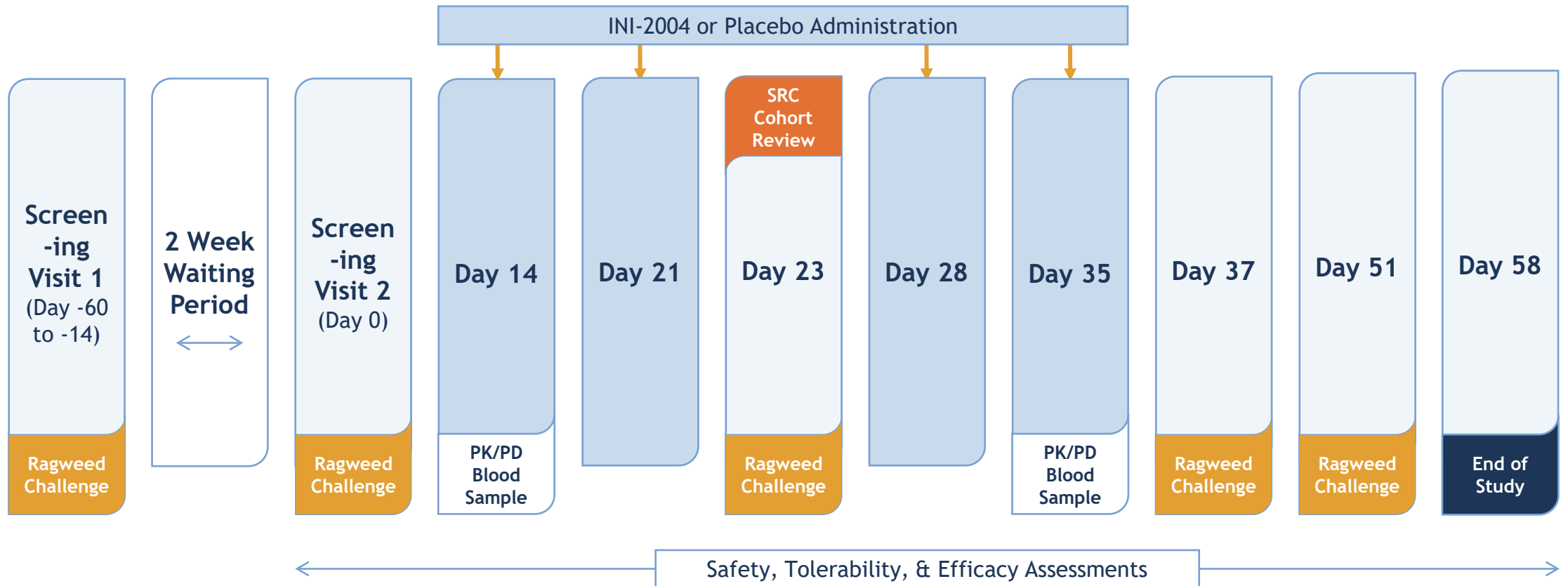
- SAD study complete
- 4 dose cohorts of healthy volunteers, up to 500 µg INI-2004 administered IN
- **INI-2004 well tolerated - no drug related serious adverse events**



Phase 1: MAD

- Four weekly doses of INI-2004 administered IN given to subjects with confirmed ragweed allergy
 - 3 dose cohorts
 - 4 weekly INI-2004 administrations
- Primary endpoints: Safety, PK (systemic INI-2004 exposure post-IN administration)
- Exploratory endpoints: Efficacy, local cytokine production, systemic antibody production

INI-2004-101 Study Design: MAD



INI-2004-101 MAD study: Patient and Safety Summary

Participant Characteristics

- 35 participants with history of ragweed-induced SAR
 - Mean age of 36, 63% female, 86% white
 - 83% with >10-year history of SAR, 20% with SAR symptoms >6 months per year
- Dose cohort breakdown
 - 125 µg cohort N=12 (9 active: 3 placebo)
 - 250 µg cohort N=12 (9 active: 3 placebo)
 - 500 µg cohort N=11 (8 active: 3 placebo)

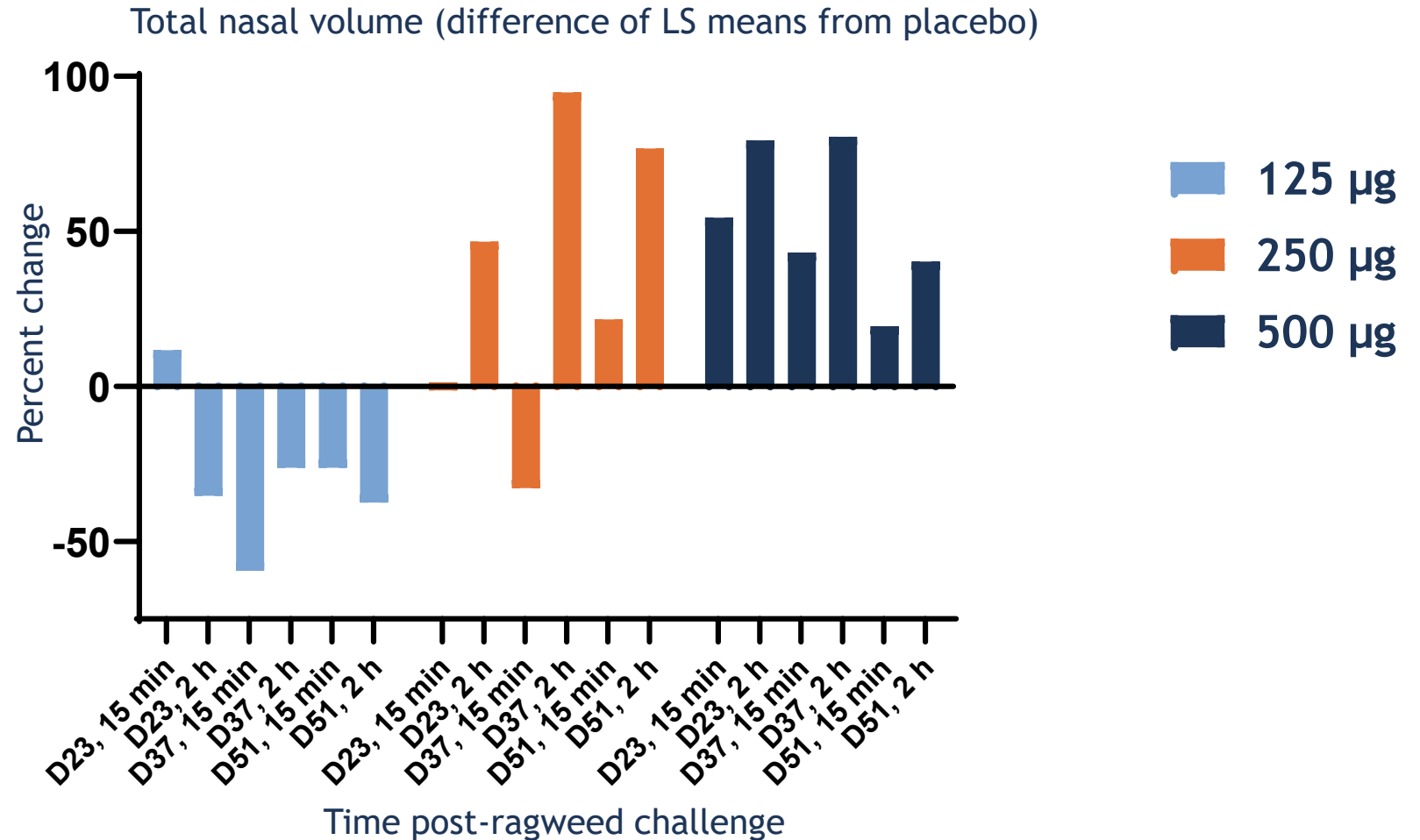
Safety Profile

- 60% of patients experienced at least one AE
 - No Serious AEs (92% of events were Grade 1/mild)
- 42% were nasal symptoms (congestion, rhinorrhea, pruritus)
 - May be associated with the route of administration
- 50% of the AEs were considered related
 - 100% of related AEs were Grade 1/mild
- INI-2004 treated
 - 73% of related events were nasal symptoms
 - Other related symptoms included nausea, dysgeusia, and fatigue
- Placebo
 - 75% of related events were nasal symptoms
 - Other symptom included lower respiratory congestion

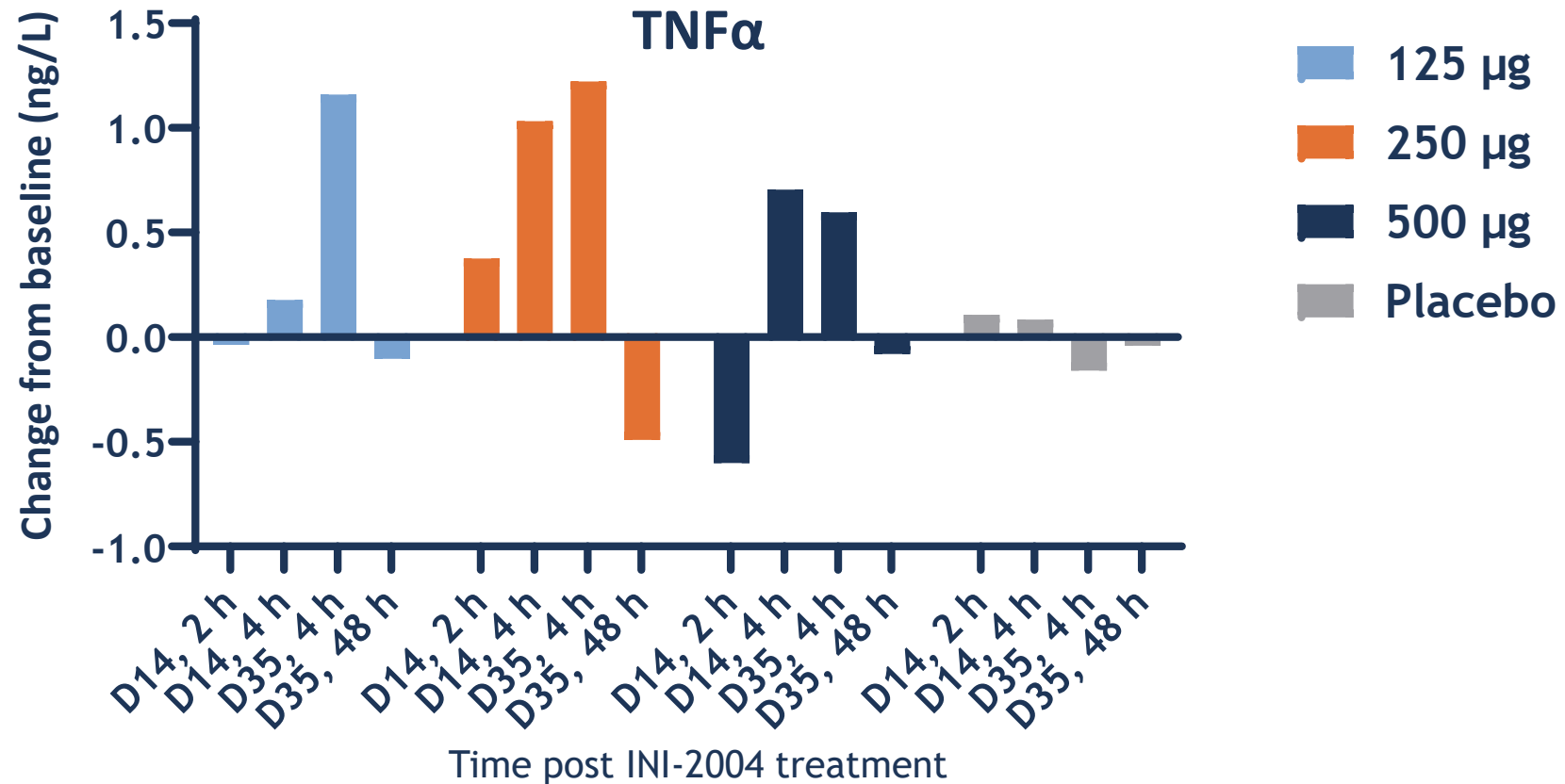
No MTD reached. Intranasal INI-2004 is safe and tolerable.

Clinical data demonstrate dose-dependent improvement in nasal congestion compared to placebo

- Treatment with **250 µg** and **500 µg** led to **34%** and **53%** improvement, respectively, in nasal congestion compared to placebo
- Improvements **lasted at least 16 days** after final INI-2004 treatment, suggesting disease modification



Clinical data demonstrate dose-dependent trends in cytokine production after INI-2004 treatment



Changes in TNF α are indicative of INI-2004 activity in humans and will be investigated as potential biomarkers in future clinical studies.

INI-2004 Next Step: Phase 2 Allergen Chamber Study

Objectives

- Confirm INI-2004 IN safety and tolerability
- Demonstrate efficacy with respect to allergy symptoms after ragweed challenge
- Inform dose response curve
- Inform onset of action and duration

Study Design

- Multi-dose, double-blind, randomized design
- N = 12 participants per group
- Study must take place outside of ragweed season
- Inclusion criteria: known ragweed allergy history, positive skin prick test, and demonstrated high TNSS scores (>6) within 2 hours of ragweed exposure
- All subjects will receive high ragweed exposure (3500 grains per m³) under controlled conditions
- Efficacy will be based on total nasal symptom scores (TNSS)
 - TNSS collected pre-ragweed exposure, throughout exposure duration, and for 48 hours after exposure
 - 48-hour TNSS collection window allow detection of both early and late ragweed responders

Intranasal INI-2004: Beyond Allergic Rhinitis

Intranasal INI-2004 product lifecycle

INI-2004 disease indications

Allergy

- IN therapy for allergic rhinitis
 - Allergen agnostic
 - Demonstrated clinical efficacy
- Oral or oral mucosal delivery for food allergy
 - Inclusion with oral mucosal immunotherapy (OMIT) or sub-lingual immunotherapy (SLIT) leads to increased antibody titers in pre-clinical models
 - Allergen specific

Infectious Disease

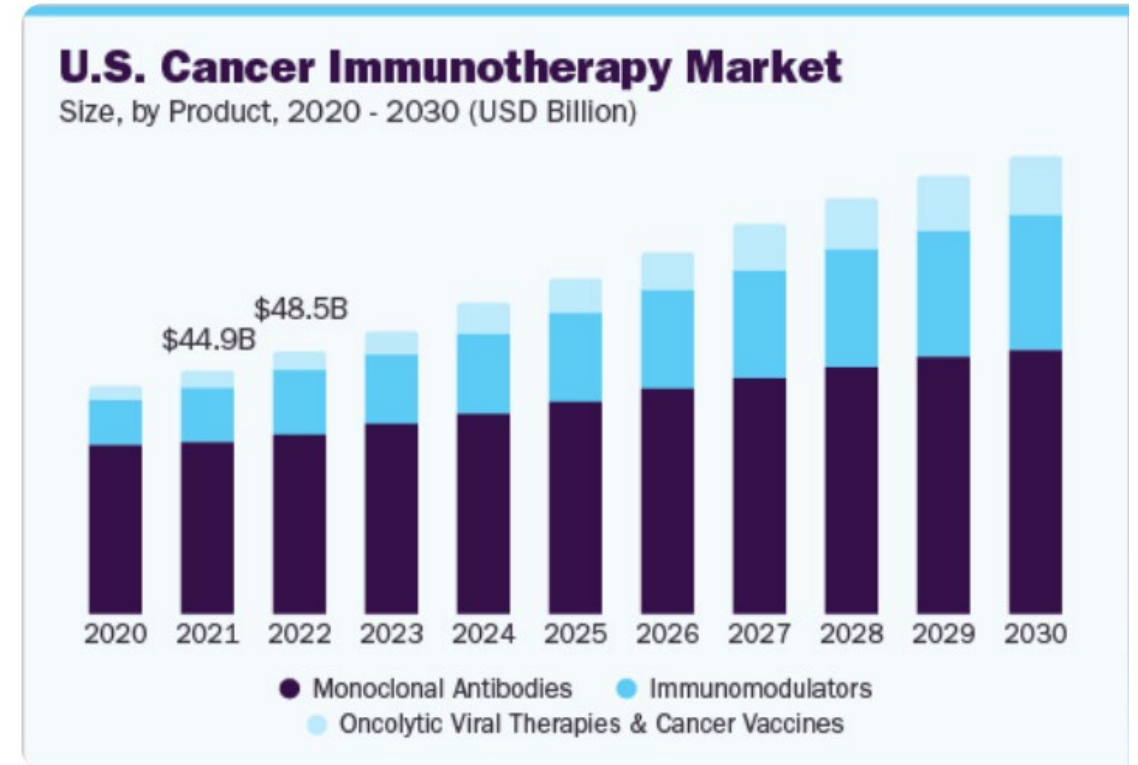
- Antigen-free vaccine
 - INI-2004 IN provides protection against lethal disease for up to 28 days in pre-clinical models
 - Antigen agnostic
 - Pandemic preparedness
- Vaccine adjuvant for recombinant antigen intranasal vaccination
 - Key targets: influenza, SARS-CoV-2, RSV, M. tuberculosis

Oncology

- Targeted cancer therapeutic via IN delivery
 - Nasopharyngeal cancer
 - Nasal and sinus cancer
 - Head and neck cancer
 - Lung cancer
- Potential for IV delivery given promising nanoparticle formulation tolerability
 - Pre-clinical data demonstrates synergy between INI-2004 and anti-OX40

Immuno-oncology market size: Worldwide IO market is large and growing

- Current global IO market estimated at ~\$125 billion USD in 2023^{1,2}
- Compound annual growth rate through 2030 is expected to be ~8.5%^{1,2}
- Growth drivers:
 1. Increased prevalence - in 2020, there were ~19.3 million cancer cases. This is estimated to grow to ~24.6 million by 2030³
 2. Awareness of cancer treatment options and a preference for immunotherapies compared to older treatment modalities (e.g. chemotherapy and radiation)^{1,2}



¹Emergen Research, Cancer Immunotherapy Market Forecast to 2030; Oct 2022

²Grand View Research, Cancer Immunotherapy Market Size & Share Report 2024-2030

³Estimate according to the International Agency for Research on Cancer (IARC)

Inimmune's Approach to Immuno-oncology

Targeted innate immune stimulation drives anti-tumor immunity

Immune suppression limits anti-tumor immunity. Innate immune receptor agonists reactivate the immune response, creating a favorable therapeutic environment.

Innate agonists for immuno-oncology:

INI-4001 (TLR7/8 agonist)

Ongoing Phase I clinical trial uses IV delivered INI-4001

- all solid tumors
- safety & efficacy as monotherapy and combination with checkpoint

Future indications: in situ cancer vaccine adjuvant in combination with antigen-releasing therapies (e.g. radiation, chemo, cryo)

INI-2004 (TLR4 agonist)

Intranasal INI-2004 safe and well tolerated in humans for repeat dosing

Pre-clinical data demonstrate efficacy in murine tumor models and synergy with anti-OX40 as well as safety in non-human primates

IN cancer indications: nasopharyngeal, nasal & sinus cancer, head & neck, lung

In situ cancer vaccine adjuvant in combination with antigen-releasing therapies (e.g. radiation, chemo, cryo)

INI-1098 (Mincle agonist)

Mincle agonist component of BCG demonstrated to be key component of efficacy against bladder cancer in pre-clinical models

INI-1098 is a synthetic Mincle agonist that could replace BCG as a safer and more tolerable bladder cancer therapy

In situ cancer vaccine adjuvant in combination with antigen-releasing therapies (e.g. radiation, chemo, cryo)

INI-4001 as Immunotherapy for 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 drugs⁵

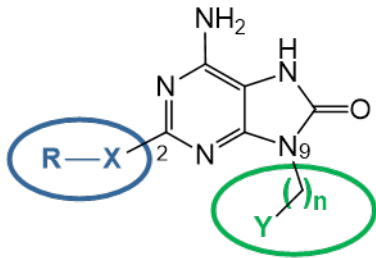
The Solution: INI-4001

- 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
- Phase 1 clinical trial
 - Open label, all solid tumors
 - Safety and efficacy of INI-4001 alone and in combination with CPI

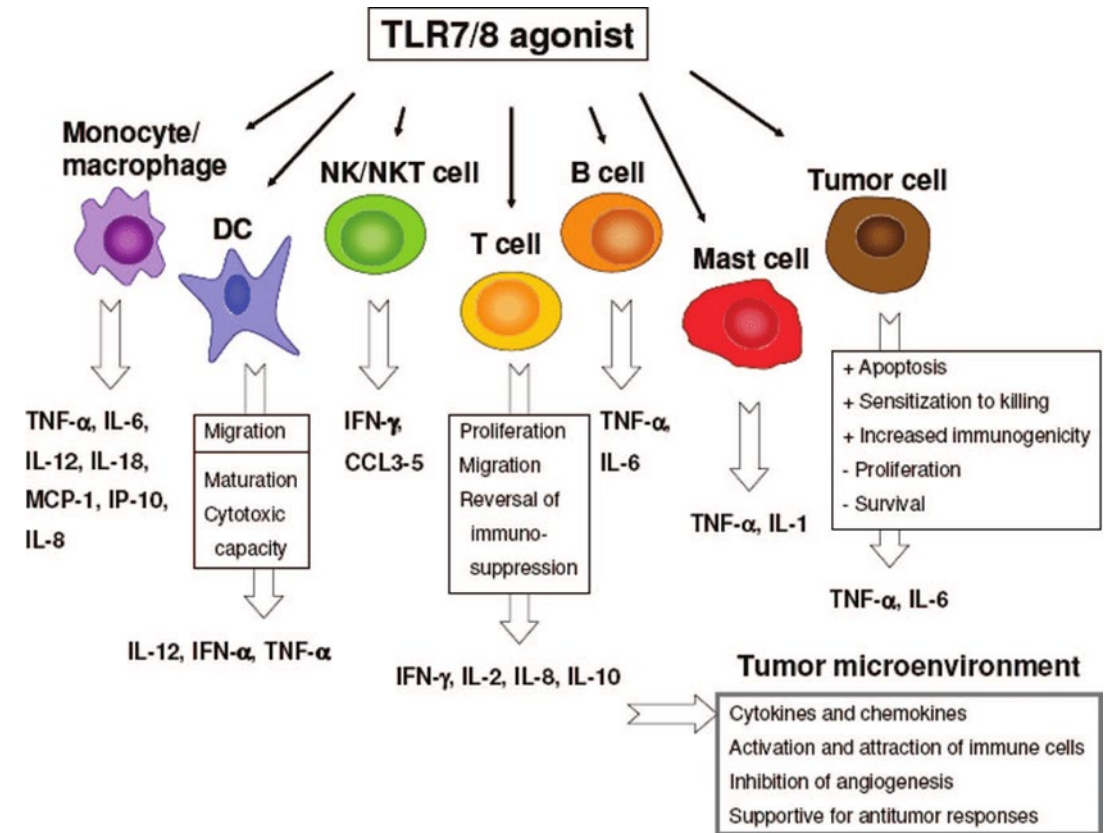
⁵Vision Research Reports, Cancer Immunotherapy Market, Global Industry Analysis, Size, Share, Growth, Trends, Revenue, Regional Outlook 2021-2030

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

The Solution: INI-4001

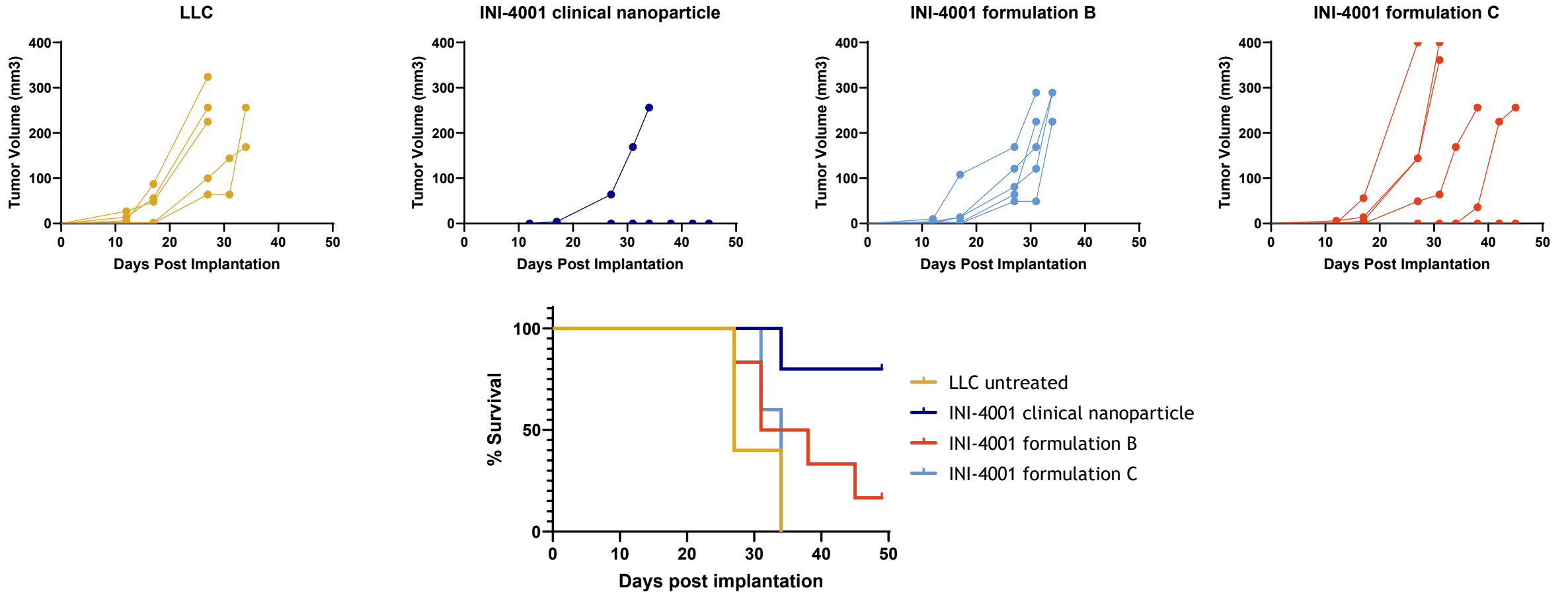


- Balanced TLR7 and TLR8 immunity profile
- Nanoparticle formulation enhances anti-tumor activity, maintaining high IFN α production while reducing pro-inflammatory TNF α
- Effective alone and in combination with anti-PD-1



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

INI-4001 Monotherapy: Optimized formulation leads to cures in Lewis Lung Carcinoma mouse model

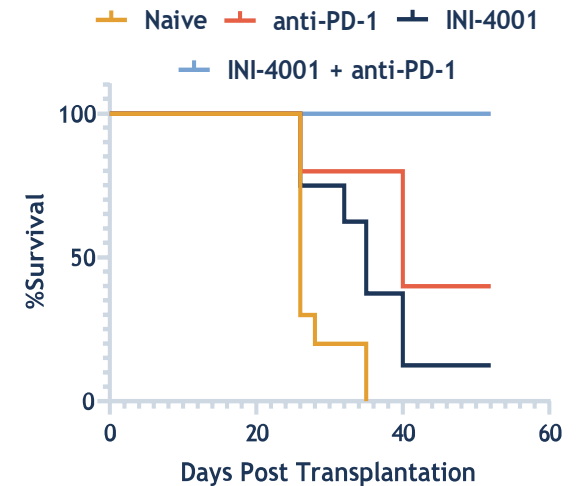
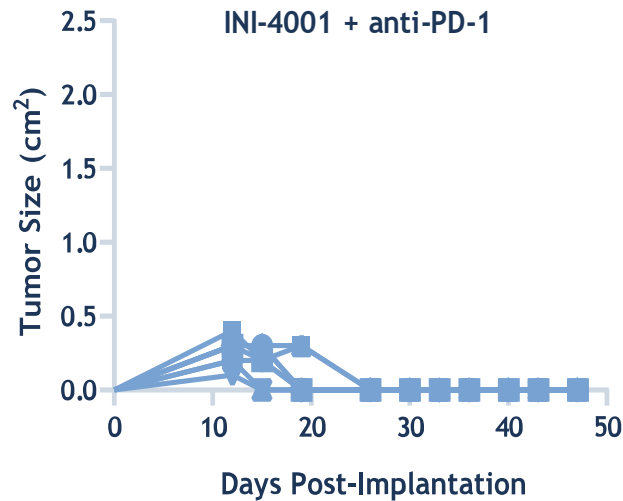
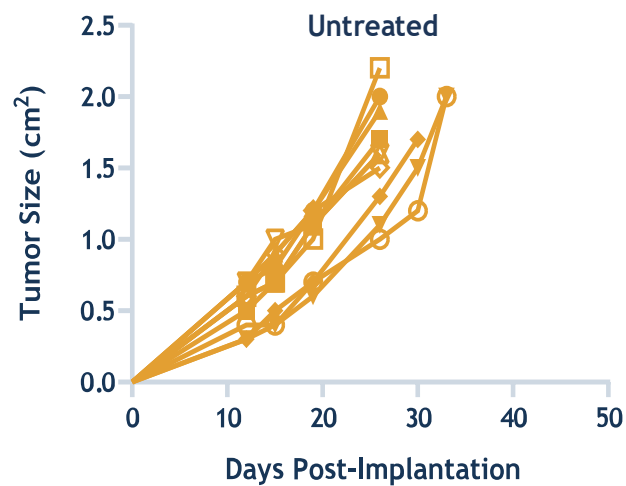


Miller, S., Beyer, C., Talbot, D., Jackson, K., Whitacre, M., Ward, J., Schoener, R., Bazin, H. and Burkhart, D., 2022, *Journal for the Immunotherapy of Cancer* Vol. 10, pp. A1211-A1211

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: 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 in continuous 21-day cycles with safety review after first 21-day cycle with single-subject dose cohorts
- 6 ascending doses planned
- If no DLTs by dose level 6, two additional subjects will be added. BOIN rules will determine MTD if DLT observed
- Primary endpoint: safety and tolerability of INI-4001
- Secondary endpoints: efficacy and biomarker identification and analysis
- Two clinical sites in Australia currently screening patients with third expected August 2024



Step 2: Combination therapy and dose expansion

- Subjects improving with INI-4001 alone continue with monotherapy
- Up to 20 additional subjects enrolled in expansion arm, all starting INI-4001 monotherapy at the same recommended dose
- All subjects with stable or progressive disease may add CPI after at least three 21-day cycles of INI-4001 alone
 - Allowable CPIs: nivolumab, pembrolizumab, cemiplimab-rwlc, avelumab, atezolizumab, durvalumab
- Treatment (monotherapy or combination) may continue as long as there is benefit
- Study will include USA sites after FDA approval
- DSMB review will identify the Recommended Phase-two Dose (RP2D) for future studies

First patient in (FPI) July 22, 2024. Dose escalation completion targeted Q1 2025.

Immunomodulators as Vaccine Adjuvants

Late-stage

Adjuvant	Description	API(s)	Formulation	Receptor	API Dev Stage	DP Dev Stage	Routes of Admin	Tox	Animal Models	Vaccine Models	Challenge Model
SAS	Synthetic AS01-like	INI-2002 + IA05	Liposomal	TLR4 + Saponin	cGMP	pre-GMP	IM	pre-clinical	Murine, Ferret	Flu, COVID	Flu
ALA	Synthetic TLR4 agonist combined with QS21, AS01 like	INI-2002 + QS21	Liposomal	TLR4 + Saponin	cGMP	pre-GMP	IM	pre-clinical	Murine, Ferret	Flu, COVID	Flu
INI-2002	Synthetic TLR4 agonist adsorbed to alum, AS04-like	INI-2002+ Alum	Aqueous 2002 on alum	TLR4	cGMP	pre-GMP	IM	pre-clinical	Murine	TB, psuedomonas, COVID	TB
INI-4001-AI	Synthetic TLR7/8 agonist adsorbed to alum, 3M052-like	INI-4001	Aqueous 4001 on alum	TLR7/8	cGMP	cGMP	IM	GLP	Murine, rat, porcine	Opioid vaccine	Fentanyl
INI-4001-Lip**	Synthetic TLR7/8 incorporated into liposome	INI-4001	Liposomal	TLR7/8	cGMP	cGMP	IM, IN, IV	GLP	Murine, porcine, baboon	Flu, COVID, pertussis, Powassan, RSV, cancer**	Flu & Powassan
INI-2004-Lip*	Synthetic TLR4 agonist, high potency	INI-2004	Liposomal	TLR4	cGMP	cGMP	IM, IN	GLP	Murine, porcine, ferret	Flu, COVID	Flu & Powassan
TRAC-478 EM	Synthetic TLR4 + TLR7/8 agonists	INI-2002 + INI-4001	Emulsion	TLR4 & TLR7/8	cGMP	cGMP in progress	IM	GLP in progress	Murine, ferret	Flu, COVID, Powassan, RSV	Flu
TRAC-478 Lip	Synthetic TLR4 + TLR7/8 agonists	INI-2002 + INI-4002	Liposomal	TLR4 & TLR7/8	cGMP	pre-GMP	IM, IN	pre-clinical	Murine	Flu, COVID, RSV	Flu

*Completed Phase I for IN allergic rhinitis

**Entering Phase I as an immunotherapeutic for cancer alone and in combination with checkpoint inhibitors

Immunomodulators as Vaccine Adjuvants

Mid & Early Stage

Adjuvant	Description	API(s)	Formulation	Receptor	API Dev Stage	DP Dev Stage	Routes of Admin	Tox	Animal Models	Vaccine Models	Challenge Model
INI-1098-Lip	Synthetic Mincle agonist, inducing robust Th17 response	INI-1098	Liposomal	Mincle	pre GMP	pre-GMP	IM, ID	pre-clinical	Murine, porcine	TB, Staph	
INI-1098-SNP	Synthetic Mincle agonist, inducing robust Th17 response	INI-1098	Silica Nanoparticle	Mincle	pre GMP	pre-GMP	IM	pre-clinical	Murine, porcine, baboon	TB, pertussis	TB
INI-3069	Synthetic STING agonist	INI-3069	Liposome	STING	pre GMP	pre-GMP	IM	pre-clinical	Murine	flu, cancer	

Partnerships & Collaborations

Our partnerships with top universities and biotech companies drives innovative technology and have generated 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.
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Development, Cofounder



Lucy Tennant, M.S.
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Physiology or Medicine for
the discovery of cancer
therapy by inhibition of
negative immune regulation



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Medical Oncology &
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Cancer Center

Internationally renowned
expert in CPI clinical trials



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Leukocare, Bone
Therapeutics, PDC*Line
Pharma, and Quantoom
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GSK Biologicals



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

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

Former President, AAAAI



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