INTROMMUNE THERAPEUTICS

Transforming Food Allergy Treatment Via a Novel Immunotherapy Technology Platform

Our Technology Will Transform How Millions Manage Food Allergies

We are developing a novel **immunotherapy technology platform** with multiple applications that reinvents how food allergies are managed in a **multi-billion $ market**.

We will transform lives by addressing the unmet needs of people living with food allergies through development of solutions that optimize **safety, efficacy, and adherence.**

Our first application targets the >$7 billion peanut allergy market

Executive Summary

Problem

FOOD ALLERGY MARKET IS IN DIRE NEED OF NEW SOLUTIONS

- **Large, growing market:** >220 million people globally with food allergies; 33 million in the U.S.
- **Suboptimal treatment options:** Current solutions do not deliver disease modification with robust safety, efficacy, and adherence profiles
- **Significant unmet need:** Causes severe health events and lifestyle impacts, with no cure

Our Solution

NEW THERAPEUTIC APPROACH FOR TREATMENT OF PEANUT AND OTHER FOOD ALLERGIES

- **Novel approach, multiple applications:** Oral Mucosal Immunotherapy (OMIT) for food allergy desensitization
- **Significant differentiation:** Dramatically reduced risk profile vs competition; built-in adherence via toothpaste delivery
- **Positive Phase 1 / 2 study results:** Met primary and secondary objectives, demonstrating safety and adherence; indications of efficacy; results presented as prestigious late-breakers at ACAAI and AAAAI conferences

Opportunity

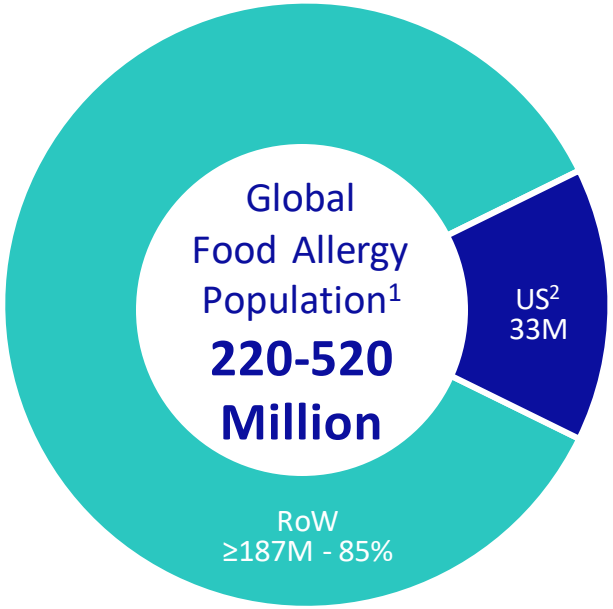
HIGH EXPECTED ROI THAT TARGETS AN ESTABLISHED, REIMBURSED MARKET

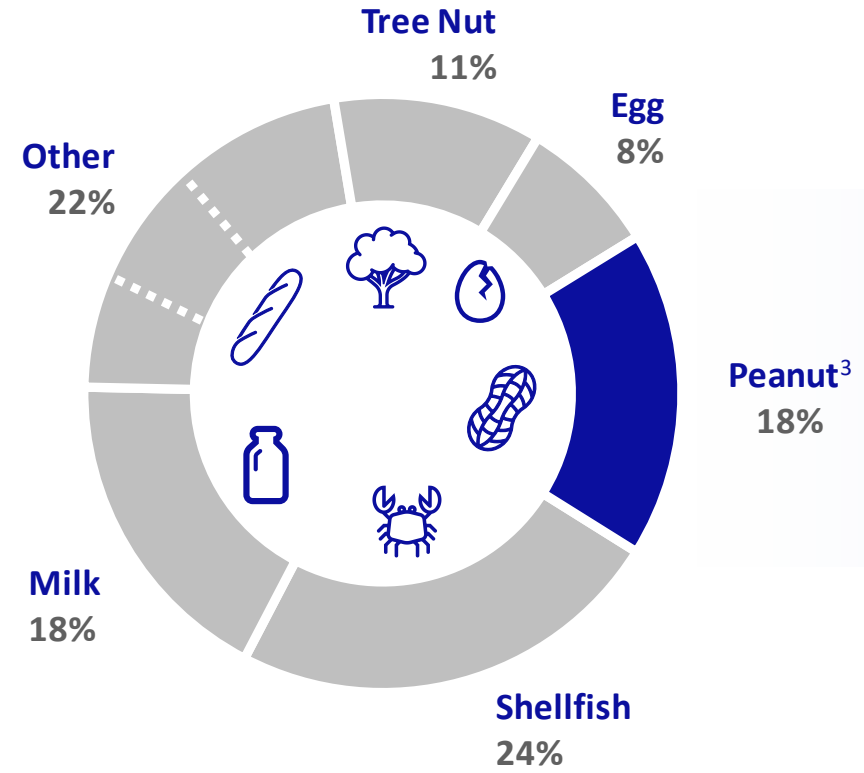
- **Multi-billion $ market:** First application targets peanut allergies; ~$7B TAM in U.S. alone
- **Opportunity with reduced risk and high expected ROI:** Recently released clinical trial results positive & provide clear direction for Phase 2 pediatric trial; strong IP portfolio
- **Minimal competition:** Only two products approved for food allergies; one is oral and approved for peanut alone; the other is an injection approved for multiple food allergies—both have limitations

Intrommune is currently seeking $38 million in Series B funding

Food Allergies Impact Millions Globally

Food allergies have become a serious public health concern as prevalence increases globally





Peanut Allergy

$7.4 Billion

TAM for U.S. market only[4]

1. FASI Our Science https://foodallergyscience.org/our-science/# Accessed November 18, 2023
2. FARE Facts and Statistics https://www.foodallergy.org/resources/facts-and-statistics Accessed November 18, 2023
3. Food Allergy Percentages from LifeSci Communications, LLC 2022
4. Intrommune Estimate

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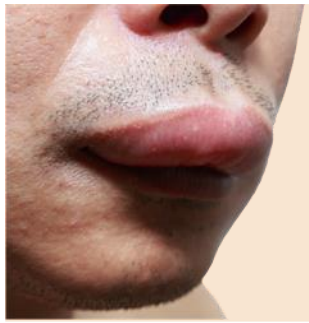
Significant Medical & Lifestyle Impacts



SEVERE HEALTH EVENTS

40-50%+

of people with food allergies have experienced a severe allergic reaction*[1]

MEDICAL CARE

200,000

Americans require emergency medical care each year for allergic reactions to food[1]

FEAR

92%

of parents feel fearful for their child's safety because of food allergies[2]

SOCIAL EXCLUSION

5 in 10

families with food allergies skip out on important school functions[2]

DISRUPTION

44%

of parents had to make a career change to care for their child with food allergies[2]

COST

$25 Billion

spent annually by U.S. families caring for children with food allergies[1]

*42% of children and 51% of adults

1. FARE Facts and Statistics https://www.foodallergy.org/resources/facts-and-statistics Accessed January 27, 2023
2. Asthma and Allergy Foundation of America, My Life with Food Allergies Survey, April 2019

Food Allergies Represent a Multi-Billion Dollar Opportunity

PEANUT ALLERGY OPPORTUNITY

TAM

$7.4 Billion
(U.S. market only)

GROWTH

Market forecasted to grow
1,700-fold
from 2017 to 2027[1]

INSURANCE COVERAGE

Yes

OIT PRICE/YEAR PER PATIENT

$10,680[2]

LARGE & GROWING UNMET NEED

6.1M
U.S. Peanut Allergic Pop

1.6M
U.S. Peanut Allergic Children

1M
Diagnosed (Aged 4 – 18 years)

690K
Immediate serviceable market for Intrommune*

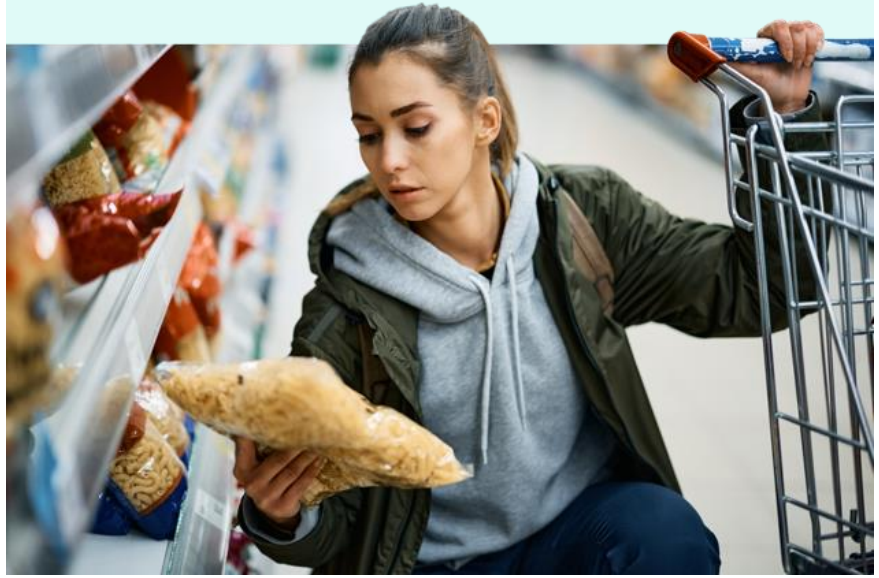
BREAKEVEN ESTIMATED IN ONLY 3 YEARS

*Assumes 60% (child), 2% (adult) seek treatment
1. GlobalData Peanut Allergy Report 2018
2. Price at January 2020 approval. price on September 10, 2023 is $14,880/year per drugs.com

No Cure & Current Solutions Are Lacking

LIMITED LIFESTYLE SOLUTIONS

- Avoidance of problem foods
- Must anxiously anticipate and prepare for the next reaction (e.g., EpiPen®)



LIMITED IMMUNOTHERAPY SOLUTIONS

- Only one oral product ever approved for food allergy (Palforzia® for peanuts)[1]
- Does not fully deliver on safety, ease of adoption, nor adherence:

Not Safe

- ~9.5% experienced anaphylaxis, which may be life-threatening[2]
- 14% use of epinephrine reported in one Phase 3 pivotal trial[2]
- >35% experienced moderate treatment-related adverse events[3]

Adoption Barriers

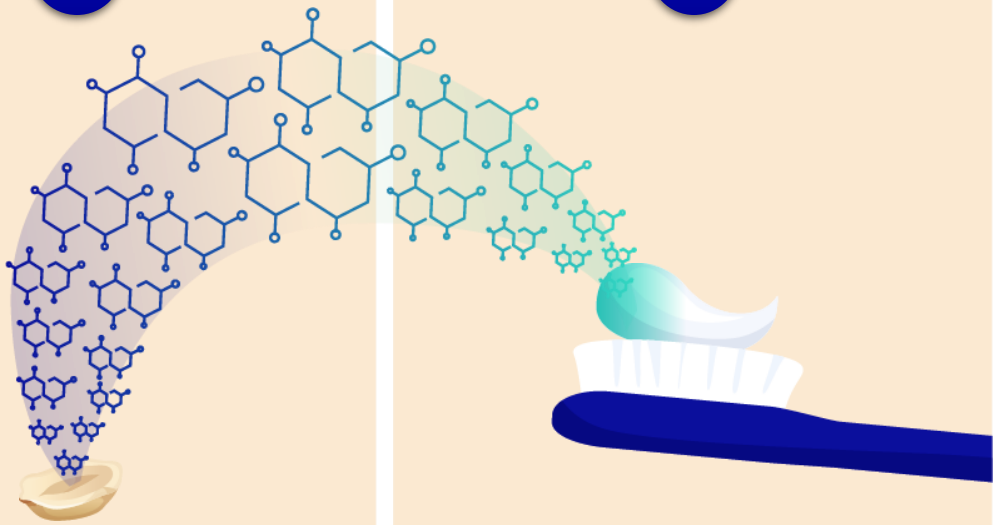
- Requires frequent visits to allergy clinic every 2 weeks for ~6 months
- 5-hour initial office visit; issue given lack of physician compensation
- Discontinuation rate of ~22%[2]

1. One injection non-disease modifying therapy has also been approved for food allergy (XOLAIR®) which has cost ($36k-$140k/year) and ease of use/adoption issues.
2. Palforzia package insert, based on pooled results of two Phase 3 studies
3. Brown KR, Baker J, Vereda A, et al. Safety of peanut (Arachis hypogaea) allergen powder-dnfp in children and teenagers with peanut allergy: Pooled summary of phase 3 and extension trials. *J Allergy Clin Immunol*. 2022;149(6):2043-2052.e9. doi:10.1016/j.jaci.2021.12.780. * Maximum severity of moderate (Grade 2)

Our Solution: Novel Technology Simplifying Allergy Immunotherapy

Food allergy desensitization transformed into easy-to-use platform via proprietary technology: Oral Mucosal Immunotherapy (OMIT)

1

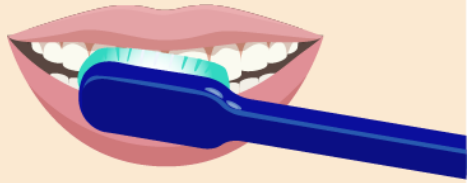


Peanut allergenic proteins (API) mechanically & chemically **extracted via proprietary methods**

2

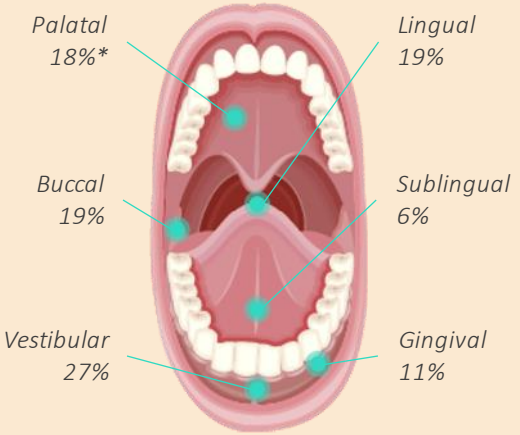
API stabilized & embedded in functional toothpaste in metered-dose dispenser

3



Immunotherapy **conveniently administered** with daily teeth brushing

4



Novel OMIT pathway leverages Langerhans cells in entire oral cavity **to reeducate immune system,** desensitizing users to allergens

*Percentages denote distribution of Langerhans cells in oral cavity. See Allam JP, et al. Allergy. 2008; 63(6):720-727

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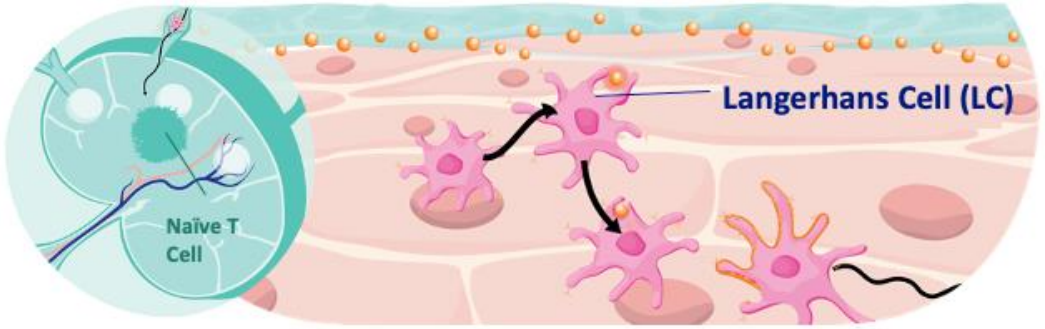
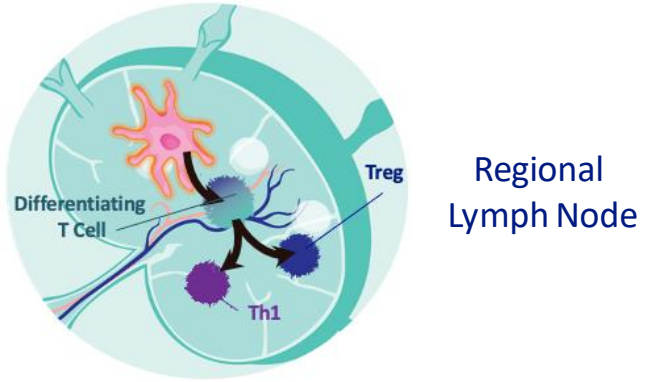
How Oral Mucosal Immunotherapy (OMIT) Works

1 **Proprietary formula delivers allergenic protein to oral cavity via toothpaste, binding to mucosa**

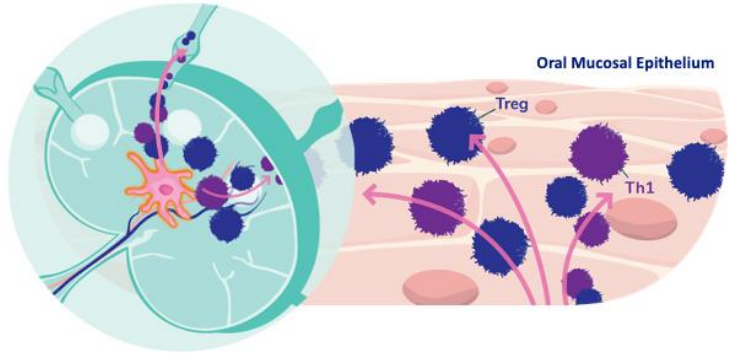
2 **Langerhans cells pull allergenic protein into the lymph system**



3 **Langerhans cells trigger the reeducation of immune system**



4 **Differentiated T cells decrease the allergic response**



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Competitor Analysis: MOA Class

	OMIT	OIT	EPIT	Injection	INT301 Commercial Benefits
Dosing/ Administration	★★★★☆	★★☆☆☆	★★★☆☆	★★☆☆☆	• No need for 4-5 hour office visit at first dose • Half the number of up-dosing visits • Physicians not hesitant to prescribe because it does not require excessive exam room/staff/resource utilization
Safety	★★★★★	★☆☆☆☆	★★★★☆	★★★★☆	• Reduce patient/caregiver hesitancy to initiate therapy due to lack of severe allergic reactions • Reduced systemic and GI side effects due to INT301 not being swallowed
Efficacy	★★★★☆	★★★★☆	★☆☆☆☆	★★★★☆	• Unsurpassed efficacy gives patients/caregivers and HCPs confidence
Adherence/ Tolerance	★★★★★	★★☆☆☆	★★★☆☆	★★☆☆☆	• Better adherence because it's something 98% of people do at least once a day; brush their teeth • Safety and efficacy profile encourages adherence • Electric toothbrush gamification and blue tooth capabilities

Reduce fears of accidental allergen exposure through daily brushing of your teeth, OMIT is a convenient, easy to use treatment that has minimal side effects and will prove to be very effective

Development Substantially Advanced for Peanut Allergy Solution

Significant progress made to advance and de-risk development

Product Development

- Process established for extracting peanut allergen protein
- Method created for stabilizing protein in functional toothpaste
- Packaging developed: pump dispenser

Regulatory

- Clear approval pathway identified
- IND filed & accepted;
  highly collaborative FDA review
- Faster path to market:
  No toxicology, pharmacokinetics or animal models required
- Exploring fast track status

Clinical

- Phase 1/2 DBPC OMEGA Trial* in adults complete
  - Met all primary and secondary safety endpoints
  - Exploratory objective provided indications of efficacy
- Due to impressive safety profile to date, FDA greenlit pediatric Phase 2 study prior to completion of our adult Phase 1 / 2 study

*Berger W. A Randomized Placebo-Controlled Phase 1 Safety Study of OMIT in Adults with Peanut Allergy [ACAAI Annual Meeting Abstract # LB011]. Ann Allergy Asthma Immunol 131 (2023) S230-S231.

Extensive Global IP Protection

IP covers all food allergens across multiple oral care formats, with 50 patents to-date

EXCLUSIVE GLOBAL IP

- For all food allergy immunotherapy
- Freedom to operate

GLOBAL PORTFOLIO

- United States
- European Union
- China
- India
- Japan

SEVERAL PATENT FAMILIES

- Immunotherapy via multiple oral care modalities
- Formulations to stabilize allergens
- Provisional applications filed - confidential

GLOBAL PROTECTION

- Expected to extend to 2049*

ADDITIONAL IP EXPECTED

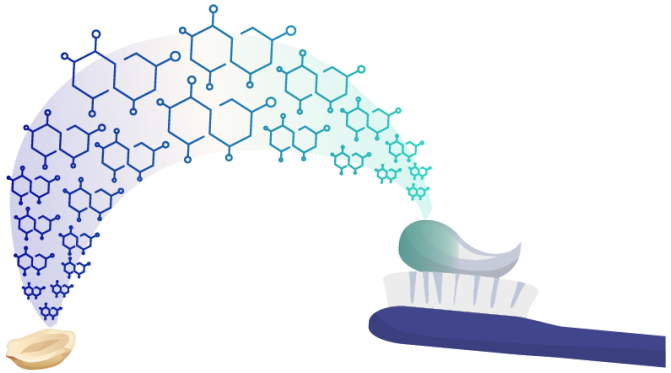
- Additional innovation
- New filings - dosing, CMC & design
- Regulatory extension
- Unique biologic – no generic pathway available

CMC = Chemistry, Manufacturing & Controls
*20-year patent term plus 5 years of regulatory extension

OMEGA Study

What is INT301?

Intrommune's goal is to reinvent how food allergies are managed by developing a new therapeutic treatment approach, oral mucosal immunotherapy (OMIT), with a significantly reduced risk profile



Our first application is INT301 for peanut allergies, immunotherapy conveniently administered with daily tooth brushing

What is the OMEGA study?

OMEGA (Oral Mucosal Escalation Goal Assessment)

- Randomized, double-blind, placebo-controlled Phase 1 / 2 study with INT301 in adults with peanut allergies*

Objectives

- Evaluate the safety of INT301 compared to placebo
- Demonstrate adherence to investigational drug product
- Explore indications of efficacy
- Provide guidance for Phase 2 study

Designed to address FDA feedback

- Concerned that toothbrushing could result in micro abrasions
- Study conducted with adults first
- Eliminated participants that had severe anaphylaxis

*Berger W. A Randomized Placebo-Controlled Phase 1 Safety Study of OMIT in Adults with Peanut Allergy [ACAAI Annual Meeting Abstract # LB011]. Ann Allergy Asthma Immunol 131 (2023) S230-S231.

Highlights from OMEGA Phase 1 / 2 Clinical Trial Results

Met primary and secondary endpoints, with indications of efficacy*

Safety

Demonstrated exemplary safety: No moderate or severe systemic reactions occurred in active participants. Non-systemic adverse reactions were mostly local (oral itching), mild, and transient

Adherence

97% adherence to study treatments

Efficacy

Exploratory objective provided indications of efficacy in difficult-to-treat adult population:

- ✓ 100% treated with toothpaste consistently tolerated the pre-specified protocol highest dose of peanut*
- ✓ 3/3 (100%) of DBPCOFC† subjects were protected to at least 600mg peanut
  - Mean dose tolerated at entry was 16mg
- ✓ Statistically significant sIgG4 increases in active arm consistent with response to treatment

Dropout

0% product-related participant dropout rate

Additional OMEGA Clinical Study Details

*Berger W. A Randomized Placebo-Controlled Phase 1 Safety Study of OMIT in Adults with Peanut Allergy [ACAAI Annual Meeting Abstract # LB011]. Ann Allergy Asthma Immunol 131 (2023) S230-S231.
†Double-Blind Placebo-Controlled Oral Food Challenge

Conclusion: OMEGA Study[1] Data Supports Advancing Development

Strong Foundation Established for Advancing into Phase 2 Trial

Based on high absolute response data, favorable risk, ease of use, and adherence profile of INT301

- **INT301 met all primary and secondary objectives**
  - Demonstrated safety of investigational product, with majority of AEs being mild with no severe AEs or anaphylaxis observed
  - Demonstrated adherence of INT301
  - No reports of dental adverse events
- **Exploratory objectives provided documented indications of efficacy**
  - Indications of immune response in the INT301 active treatment arm based on increase in sIgG4
  - Decrease in IgE/IgG4 ratio
  - Indications of efficacy in a difficult to treat, adult population
- **Expect greater effect size in planned large Phase 2 pediatric trial based on learnings and experience of other investigators**

Berger W. A Randomized Placebo-Controlled Phase 1 Safety Study of OMIT in Adults with Peanut Allergy [ACAAI Annual Meeting Abstract # LB011]. Ann Allergy Asthma Immunol 131 (2023) S230-S231.

Top-Line Results Presented at ACAAI & AAAAI

Generated >140 pieces of news coverage, reaching total potential audience of 7 billion

Late-Breaking ACAAI Abstract

- Oral presentation given Nov. 11, 2023 at American College of Allergy, Asthma and Immunology Scientific Meeting
- Published in November issue of Annals of Allergy, Asthma, and Immunology

Late-Breaking AAAAI Abstract

- Oral presentation given Feb. 23, 2024 at American Academy of Allergy, Asthma and Immunology Scientific Meeting

Media Coverage

- Press release picked up by 362 outlets, generating 143 instances of news coverage in the first few days:

Online/Print

REUTERS, Medscape, FAST COMPANY, WebMD, Allergic Living, Healio, UPTOWN ALLERGY & ASTHMA, MBN MARKET BUSINESS NEWS, MEDICAL NEWS TODAY, ScienceDirect

TV

abc NEWS, FOX NEWS, NBC NEWS

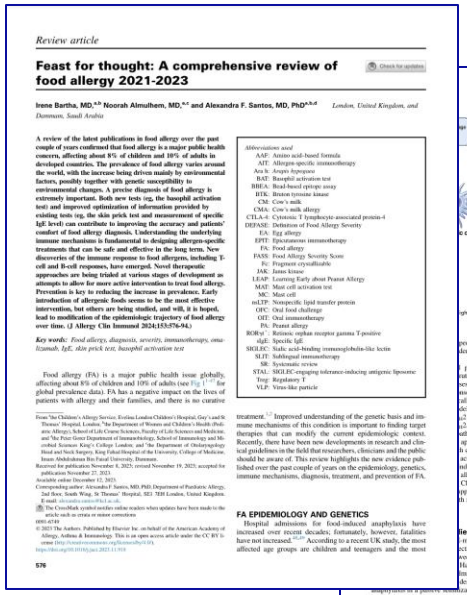
"This toothpaste offers an easier option that families can fit into their everyday schedules... I'm always looking for options like that."

Kristin Sokol
MD, MPH, FAAAAI
Allergist & Immunologist at Schreiber Allergy

schreiber allergy

Full data set to be reported in 2024

Independent Physicians are Recognizing OMIT



Review article

Feast for thought: A comprehensive review of food allergy 2021-2023

Irene Bartha, MD,[a,b] Noorah Almulhem, MD,[a,c] and Alexandra F. Santos, MD, PhD[a,b,d] *London, United Kingdom, and Dammam, Saudi Arabia*

A review of the latest publications in food allergy over the past couple of years confirmed that food allergy is a major public health concern, affecting about 8% of children and 10% of adults in developed countries. The prevalence of food allergy varies around the world, with the increase being driven mainly by environmental factors, possibly together with genetic susceptibility to environmental changes. A precise diagnosis of food allergy is extremely important. Both new tests (eg, the basophil activation test) and improved optimization of information provided by existing tests (eg, the skin prick test and measurement of specific IgE level) can contribute to improving the accuracy and patients' comfort of food allergy diagnosis. Understanding the underlying immune mechanisms is fundamental to designing allergen-specific treatments that can be safe and effective in the long term. New discoveries of the immune response to food allergens, including T-cell and B-cell responses, have emerged. Novel therapeutic approaches are being trialed at various stages of development as attempts to allow for more active intervention to treat food allergy. Prevention is key to reducing the increase in prevalence. Early introduction of allergenic foods seems to be the most effective intervention, but others are being studied, and will, it is hoped, lead to modification of the epidemiologic trajectory of food allergy over time. (J Allergy Clin Immunol 2024;153:576-94.)

Key words: Food allergy, diagnosis, severity, immunotherapy, omalizumab, IgE, skin prick test, basophil activation test

Abbreviations used
AAF: Amino acid–based formula
AIT: Allergen-specific immunotherapy
Ara h: *Arachis hypogaea*
BAT: Basophil activation test
BHEA: Bead-based epitope assay
BTK: Bruton tyrosine kinase
CM: Cow's milk
CMA: Cow's milk allergy
CTLA-4: Cytotoxic T lymphocyte–associated protein-4
DEPASE: Definition of Food Allergy Severity
EA: Egg allergy
EPIT: Epicutaneous immunotherapy
FA: Food allergy
FASS: Food Allergy Severity Score
Fc: Fragment crystallizable
JAK: Janus kinase
LEAP: Learning Early about Peanut Allergy
MAT: Mast cell activation test
MC: Mast cell
nsLTP: Nonspecific lipid transfer protein
OFC: Oral food challenge
OIT: Oral immunotherapy
PA: Peanut allergy
RORγt: Retinoic orphan receptor gamma T-positive
sIgE: Specific IgE
SIGLEC: Sialic acid–binding immunoglobulin-like lectin
SLIT: Sublingual immunotherapy
SR: Systematic review
STAL: SIGLEC-engaging tolerance-inducing antigenic liposome
Treg: Regulatory T
VLP: Virus-like particle

Food allergy (FA) is a major public health issue globally, affecting about 8% of children and 10% of adults (see Fig 1)[1-3] for global prevalence data). FA has a negative impact on the lives of patients with allergy and their families, and there is no curative treatment.[1,2] Improved understanding of the genetic basis and immune mechanisms of this condition is important to finding target therapies that can modify the current epidemiologic context. Recently, there have been new developments in research and clinical guidelines in the field that researchers, clinicians and the public should be aware of. This review highlights the new evidence published over the past couple of years on the epidemiology, genetics, immune mechanisms, diagnosis, treatment, and prevention of FA.

FA EPIDEMIOLOGY AND GENETICS

Hospital admissions for food-induced anaphylaxis have increased over recent decades; fortunately, however, fatalities have not increased.[4C,4F] According to a recent UK study, the most affected age groups are children and teenagers and the most

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Received for publication November 8, 2023; revised November 19, 2023; accepted for publication November 27, 2023.
Available online December 12, 2023.
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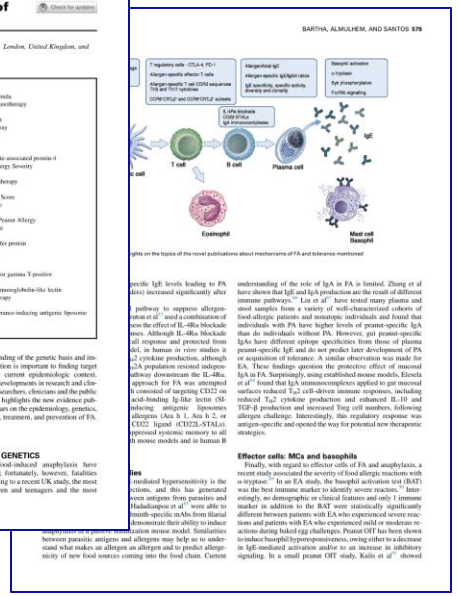
https://doi.org/10.1016/j.jaci.2023.11.910



specific IgE levels leading to PA ders) increased significantly after

pathway to suppress allergen- uton et al[37] used a combination of sess the effect of IL-4Rα blockade ses. Although IL-4Rα blockade all response and protected from ded, in human in vitro studies it 2 cytokine production, although gA population resisted indepen- athway downstream the IL-4Rα. approach for FA was attempted h consisted of targeting CD22 on acid-binding Ig-like lectin (SI- nhibiting antigenic liposomes allergens (Ara h 1, Ara h 2, or CD22 ligand (CD22L-STALs) ppressed systemic memory to all h mouse models and in human B

lies
-mediated hypersensitivity is the ections, and this has generated ween antigens from parasites and Hadadianpour et al[38] were able to limith-specific mAbs from filarial demonstrate their ability to induce nmunization mouse model. Similarities between parasitic antigens and allergens may help us to understand what makes an allergen an allergen and to predict allergenicity of new food sources coming into the food chain. Current

understanding of the role of IgA in FA is limited. Zhang et al have shown that IgE and IgA production are the result of different immune pathways.[39] Liu et al[40] have tested many plasma and stool samples from a variety of well-characterized cohorts of food-allergic patients and nonatopic individuals and found that individuals with PA have higher levels of peanut-specific IgA than do individuals without PA. However, gut peanut-specific IgAs have different epitope specificities from those of plasma peanut-specific IgE and do not predict later development of PA or acquisition of tolerance. A similar observation was made for EA. These findings question the protective effect of mucosal IgA in FA. Surprisingly, using established mouse models, Elissela et al[41] found that IgA immunocomplexes applied to gut mucosal surfaces reduced T_H2 cell–driven immune responses, including reduced T_H2 cytokine production and enhanced IL-10 and TGF-β production and increased Treg cell numbers, following allergen challenge. Interestingly, this regulatory response was antigen-specific and opened the way for potential new therapeutic strategies.

Effector cells: MCs and basophils

Finally, with regard to effector cells of FA and anaphylaxis, a recent study associated the severity of food allergic reactions with α-tryptase.[42] In an EA study, the basophil activation test (BAT) was the best immune marker to identify severe reactors.[43] Interestingly, no demographic or clinical features and only 1 immune marker in addition to the BAT were statistically significantly different between patients with EA who experienced severe reactions and patients with EA who experienced mild or moderate reactions during baked egg challenges. Peanut OIT has been shown to induce basophil hyporesponsiveness, owing either to a decrease in IgE-mediated activation and/or to an increase in inhibitory signaling. In a small peanut OIT study, Kulis et al[44] showed

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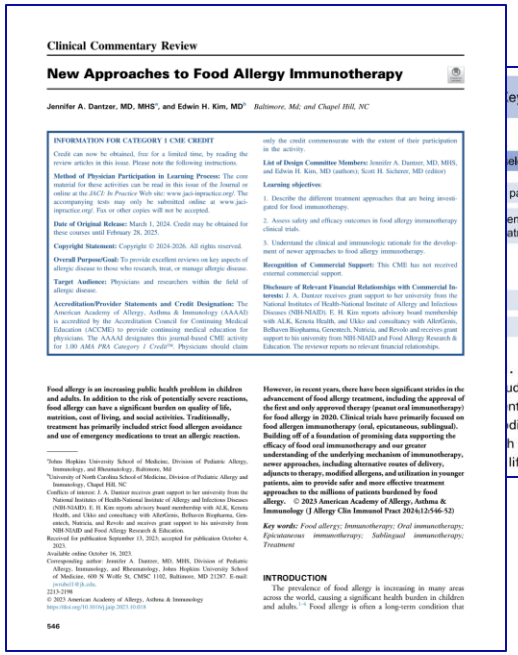

Clinical Commentary Review

New Approaches to Food Allergy Immunotherapy

Jennifer A. Dantzer, MD, MHS[a], and Edwin H. Kim, MD[b] *Baltimore, Md; and Chapel Hill, NC*

INFORMATION FOR CATEGORY 1 CME CREDIT

Credit can now be obtained, free for a limited time, by reading the review articles in this issue. Please note the following instructions.

Method of Physician Participation in Learning Process: The core material for these activities can be read in this issue of the Journal or online at the *JACI: In Practice* Web site: www.jaci-inpractice.org/. The accompanying tests may only be submitted online at www.jaci-inpractice.org/. Fax or other copies will not be accepted.

Date of Original Release: March 1, 2024. Credit may be obtained for these courses until February 28, 2025.

Overall Purpose/Goal: To provide excellent reviews on key aspects of allergic disease to those who research, treat, or manage allergic disease.

Target Audience: Physicians and researchers within the field of allergic disease.

Accreditation/Provider Statements and Credit Designation: The American Academy of Allergy, Asthma & Immunology (AAAAI) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The AAAAI designates this journal-based CME activity for 1.00 *AMA PRA Category 1 Credit™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

List of Design Committee Members: Jennifer A. Dantzer, MD, MHS, and Edwin H. Kim, MD (authors); Scott H. Sicherer, MD (editor)

Learning objectives:

1. Describe the different treatment approaches that are being investigated for food immunotherapy.
2. Assess safety and efficacy outcomes in food allergy immunotherapy clinical trials.
3. Understand the clinical and immunologic rationale for the development of newer approaches to food allergy immunotherapy.

Recognition of Commercial Support: This CME has not received external commercial support.

Disclosure of Relevant Financial Relationships with Commercial Interests: J. A. Dantzer receives grant support to her university from the National Institutes of Health-National Institute of Allergy and Infectious Diseases (NIH-NIAID). E. H. Kim reports advisory board membership with ALK, Kenota Health, and Ukko and consultancy with AllerGenis, Bellhaven Biopharma, Genentech, Nutricia, and Revolo and receives grant support to his university from NIH-NIAID and Food Allergy Research & Education. The reviewer reports no relevant financial relationships.

Food allergy is an increasing public health problem in children and adults. In addition to the risk of potentially severe reactions, food allergy can have a significant burden on quality of life, nutrition, cost of living, and social activities. Traditionally, treatment has primarily included strict food allergen avoidance and use of emergency medications to treat an allergic reaction.

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Conflicts of interest: J. A. Dantzer receives grant support to her university from the National Institutes of Health-National Institute of Allergy and Infectious Diseases (NIH-NIAID). E. H. Kim reports advisory board membership with ALK, Kenota Health, and Ukko and consultancy with AllerGenis, Bellhaven Biopharma, Genentech, Nutricia, and Revolo and receives grant support to his university from NIH-NIAID and Food Allergy Research & Education.
Received for publication September 13, 2023; accepted for publication October 4, 2023.
Available online October 16, 2023.
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2213-2198

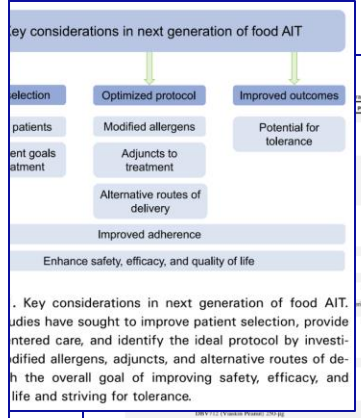
https://doi.org/10.1016/j.jaip.2023.10.018

However, in recent years, there have been significant strides in the advancement of food allergy treatment, including the approval of the first and only approved therapy (peanut oral immunotherapy) for food allergy in 2020. Clinical trials have primarily focused on food allergen immunotherapy (oral, epicutaneous, sublingual). Building off of a foundation of promising data supporting the efficacy of food oral immunotherapy and our greater understanding of the underlying mechanism of immunotherapy, newer approaches, including alternative routes of delivery, adjuncts to therapy, modified allergens, and utilization in younger patients, aim to provide safer and more effective treatment approaches to the millions of patients burdened by food allergy. **(J Allergy Clin Immunol Pract 2024;12:546-52)**

Key words: Food allergy; Immunotherapy; Oral immunotherapy; Epicutaneous immunotherapy; Sublingual immunotherapy; Treatment

INTRODUCTION

The prevalence of food allergy is increasing in many areas across the world, causing a significant health burden in children and adults.[1-3] Food allergy is often a long-term condition that



. Key considerations in next generation of food AIT. udies have sought to improve patient selection, provide ntered care, and identify the ideal protocol by investi- dified allergens, adjuncts, and alternative routes of de- h the overall goal of improving safety, efficacy, and life and striving for tolerance.

Phase	Population	Treatment duration	Primary end point
III	1-55 y with peanut allergy and ≥2 other food allergies (milk, egg, wheat, cashew, hazelnut, walnut)	16-20 wk	≥600 mg single dose of peanut without dose-limiting symptoms
IIb	6-25 y with allergy to ≥3 foods (peanut, milk, egg, wheat, oat, soy, barley, rye, buckwheat, hazelnut, pecan, cashew, pistachio, almond, walnut, sesame)	52 wk	Time-to-maintenance (1500 mg) during multifood OIT protocol
II	4-55 y with peanut and 1-2 other food allergies (milk, almond, shellfish, fish, cashew, hazelnut, egg, walnut, sesame, soy, wheat)	44 wk	≥1043 cumulative dose without dose-limiting symptoms to (1) peanut, (2) peanut and ≥1 other food, (3) peanut and 2 other foods
II	6-17 y with peanut allergy	Up to 40 wk	≥2044 mg cumulative dose of peanut
II	4-30 y with cow's milk allergy	18 wk	≥2040 mg cumulative dose of cow's milk
III	4-17 y with peanut allergy	12 mo	≥1043 mg cumulative dose of peanut
...sitivity trial	1-17 y with peanut allergy	18 mo	8-wk sustained unresponsiveness
III	12-55 y with peanut allergy	7 wk 23 wk	Number of participants with treatment-related adverse events Geometric mean of the maximum tolerated dose of peanut protein at DBPCFC ↑
III	4-7 y with peanut allergy	12 mo	(1) If initial ED is ≤30 mg: ED is ≥300 mg peanut (2) If initial ED is ≥30 mg: ED is ≥600 mg peanut
III	2-5 y with peanut allergy: completed the PIPTOPE study	36 mo	ED ≥ 1000 mg at 12, 24, and 36 mo
	patch		
SLIT			
	ALLIANCE trial NCT03440463	1	4-65 y with peanut allergy 2 wk	Incidence of local application-site reactions
Modified allergens			

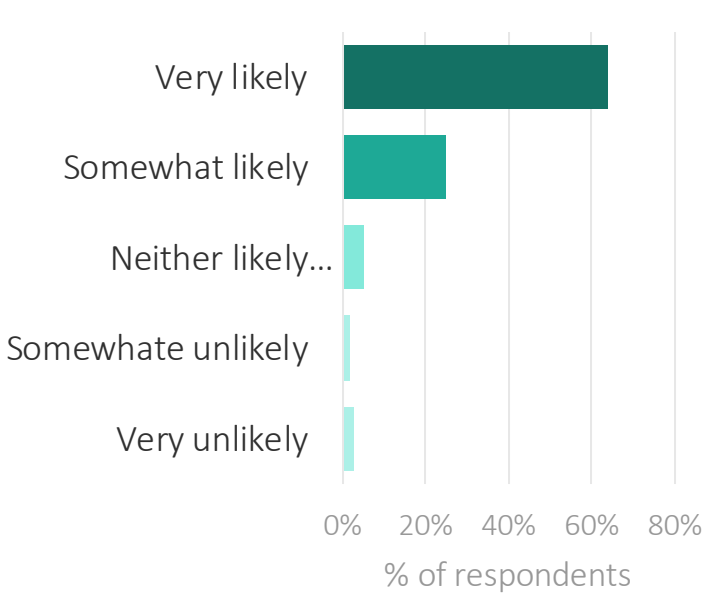
The Journal of Allergy and Clinical Immunology: In Practice

Full data set to be reported in 2024

INTROMMUNE THERAPEUTICS

Strong HCP & Consumer Interest in Intrommune's OMIT Solution

Patients



Healthcare Professionals

"I was pleased to see a Late Breaking Abstract introducing Oral Mucosal Immunotherapy (OMIT) as a new treatment option for peanut allergies. OMIT is being studied to ***address the large, unmet need in food allergies*** *by providing a convenient, safe and effective choice which is administered in a fully-functional toothpaste that is incorporated into the patient's daily routine activities"*

Todd Mahr
MD, FACAAI, FAAAAI,

Executive Medical Director, ACAAI
Pediatric Allergist, Gundersen Health System

GUNDERSEN HEALTH SYSTEM

American College of Allergy, Asthma & Immunology

"The results of the OMEGA trial demonstrate the safety of INT301 for adults with peanut allergy. The exploratory findings also support its potential as an effective treatment to protect patients from accidental peanut exposure. By embedding the proteins in a fully-functional toothpaste, and ***addressing many of the concerns associated with existing peanut immunotherapy****, INT301 is being developed to address the unmet needs in the market"*

Michael S. Blaiss
MD, FACAAI, FAAAAI

Clinical Professor, Medical College of Georgia at Augusta

AUGUSTA UNIVERSITY MEDICAL COLLEGE OF GEORGIA

Allergy and Asthma Network consumer survey, October 2018 (n=137)

Go-to-Market Plan Targets Allergists Seeking FDA-Approved Solutions

Target is the large number of allergists who currently do not treat food allergies due to lack of safety, legal risk & complicated dosing protocols

~300 Allergists

Prescribe off-label "home-brew" food allergy solutions

~6000 Allergists[1]

Lack FDA-approved solutions with strong efficacy/safety profile to offer their food allergy patients

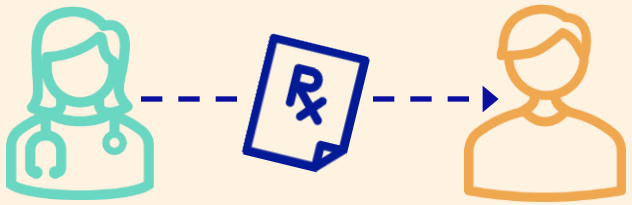
= ~200 allergists/immunologists

1. ABAI.org

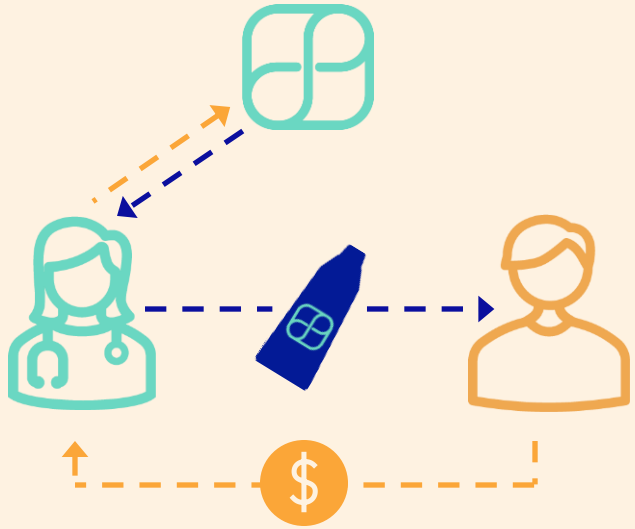
Competitively Differentiated Business Model Will Drive HCP Support

Buy-and-bill model during initiation/up-dosing, transitioning to Rx mail order for maintenance

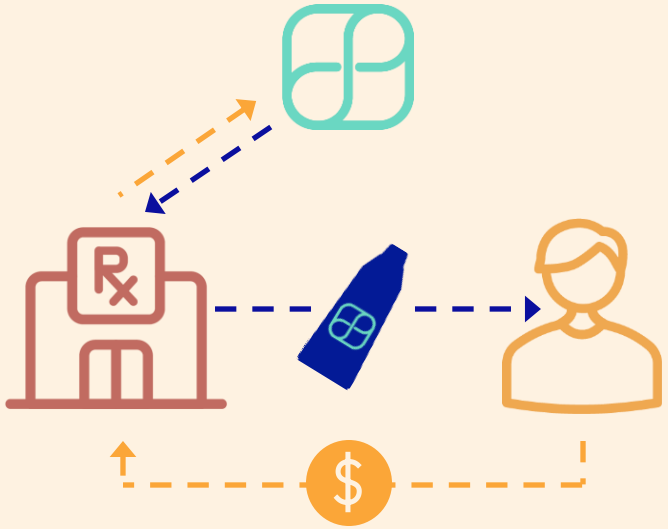
Food allergy confirmed via test*; doctor prescribes Intrommune INT301



HCP sells to patient in-office via “buy & bill” model for initiation & up-dosing



Transitions to prescription mail order pharmacy for maintenance



*Patient history, blood test, skin prick test and possibly an oral food challenge

Targeted, Highly Efficient Demand Generation Model

Shape the Market

Drive awareness and interest in OMIT as a new & better solution

- Activate MSLs 2-2.5 years in advance
  - Medical conferences
  - KOL engagement
  - Publications
  - Webinars/presentations
  - Educational web content
- PR & social/influencer marketing to patients 12-18 months in advance

Drive HCP Recommendations

Influence top prescribers & thought leaders amongst ~6000 targeted allergists

- 80-person sales force will cover 70-80% of target universe
- Leverage rent-to-own sales model
- Start with smaller # of high-prescribers at high call frequency, then expand reach over time
- Focus on the large allergy practices (such as Allergy Partners and Family Allergy) to drive quick, targeted uptake

Ignite Consumer Demand

Engage directly with consumers to get them to ask a doctor for INT301

- DTC advertising (once critical mass of HCP awareness achieved)
  - Geo-targeted TV & digital ads
  - Lead capture, email nurture, local doctor finder
- Augment with in-office promotion
  - Promotional materials
  - QR code linked to website

Series B Funding Requirements

$38 million in funding for Phase 2 pediatric study and for pipeline development

Series A and Bridge
$10 Million

Accomplished

- Exclusive global rights to OMIT for food allergy
- INT301 formulation developed
- IND accepted
- Completed Phase 1 / 2 (adults)

Investors

RobinHood VENTURES

RED BEAR ANGELS

Chemical Angel Network

TIMBERLINE

Series B
$38 Million

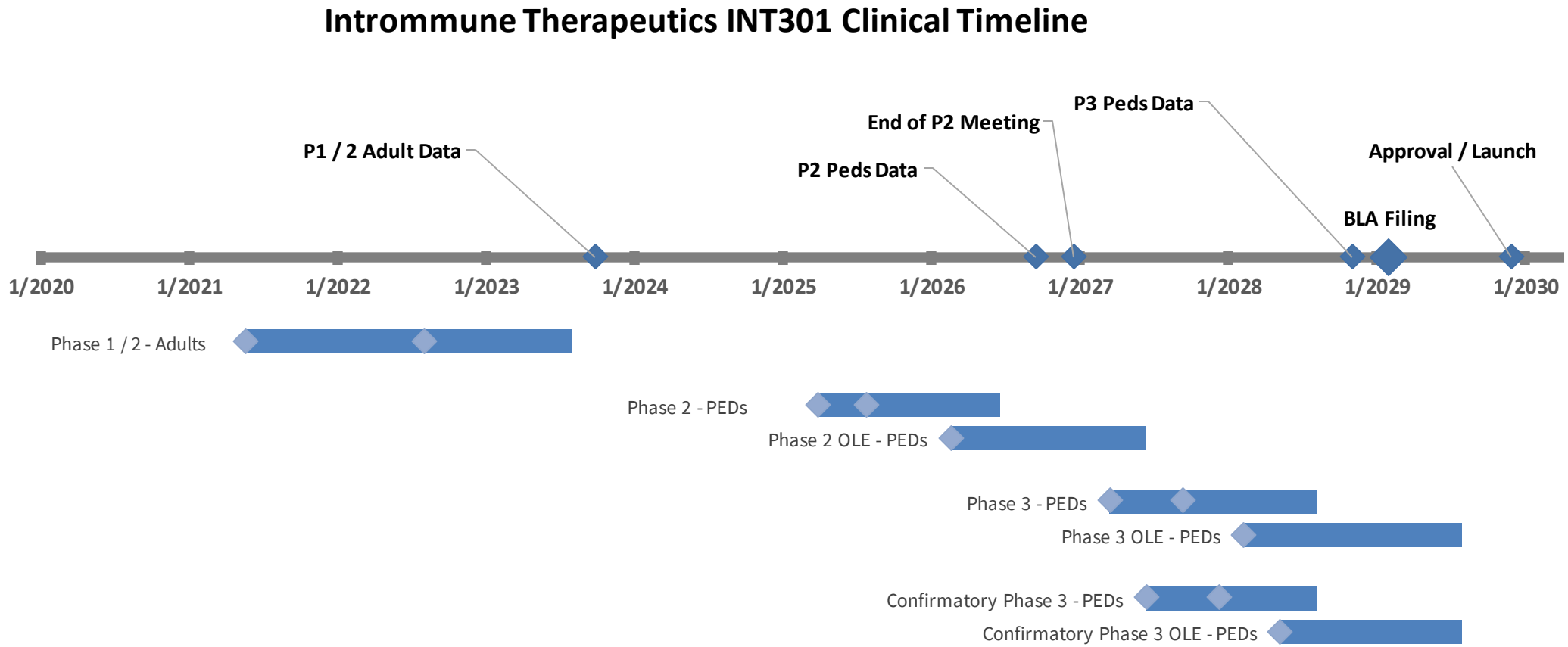
Goals

- Finalize drug product specifications
- Complete Phase 2 clinical trial in pediatric population
- Incorporate Phase 2 learnings into Phase 3 plans
- Identify strategic and market partner/opportunities
- Product development to expand to new indications, multi-food therapy and enhance immunotherapy through innovative technologies
- Shape market and establish Medical Advisory Board

Series B Funding Will Cover Phase 2 Studies

Clinical Roadmap (INT301)

Series B **$38M**



INTROMMUNE THERAPEUTICS

Experienced Leadership Team

Experience successfully bringing innovation to market, including in biotech, pharma and allergy markets:

ALK ABELLÓ

MERCK

gsk GlaxoSmithKline

teva

MEDA PHARMACEUTICALS

American College of Allergy, Asthma & Immunology

NEUROGASTRX

PerkinElmer

NOCENDRA, Inc. Controlling Inflammation Naturally

Michael Nelson, JD
Chief Executive Officer

Ray Forslund
Head of Chemistry, Manufacturing & Controls

Stuart Loesch
President & Chief Commercial Officer

William Berger, MD, MBA
Head of Medical Affairs

Nandini Murthy
Head of Regulatory

Christopher Schuster, MBA
Chief Financial Officer

Opportunity to Get in Early on Technology with High Expected ROI

Intrommune offers attractive opportunity that targets an established, reimbursed market

- ✓ **Large, growing market** with established reimbursement – Peanut allergy TAM of ~$7B in U.S. alone
- ✓ **Multiple applications & opportunities** enabled by unique immunotherapy platform technology
- ✓ **Minimal competition** - Only one peanut allergy product ever approved for any food allergy
- ✓ **OMIT highly differentiated** vs. current OIT solution, with expected safety, efficacy & adherence benefits:
  - Intrommune's Peanut INT301 is best-in-class agent – 9 in 10 subjects[1] will use
  - Opportunity to position as "maintenance product of choice"
  - Expect concomitant use with monoclonal antibodies
- ✓ **Phase 1 clinical trial completed, demonstrating safety, adherence and ease-of-use with indications of efficacy**
- ✓ **Comparator Aimmune acquired for $2.6 billion** with Palforzia product only 1 in 10 subjects[2] will use; administered via GI tract, has significant side effects, is difficult to administer, experiences poor patient adherence

1. Marketing survey of 137 peanut allergy patients and parents. https://www.globenewswire.com/en/news-release/2020/02/03/1978768/0/en/Survey-Confirms-Physician-Interest-in-Peanut-Allergy-Immunotherapy.html.
2. Patrawala S, et al. Real-World Adoption of FDA-approved Peanut Oral Immunotherapy with Palforzia. *J Allergy Clin Immunol Pract*. 2022 Apr;10(4):1120-1122.e1. (Presented as Poster #343 at the AAAAI 2021 Annual Meeting).

Disclosures

Important Information

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This communication contains forward-looking statements, which can be identified by, among other things, the use of forward-looking language, such as the words "plans," "intends," "believes," "expects," "anticipates," "estimates," "projects," "potential," "may," "will," "would," "could," "should," "seeks," or "scheduled to," or other similar words, or by discussion of strategy or intentions. Forward-looking statements are based upon management's present expectations or strategies regarding the future and are subject to known and unknown risks and uncertainties that could cause actual results, events or developments to be materially different from those indicated in such forward-looking statements. No assurance can be given that the future results covered by the forward-looking statements will be achieved. The information contained herein and in the documents enclosed herewith is current only as of the date hereof and you should not, under any circumstances, assume that there has not been any change in the matters discussed herein or in the documents enclosed herewith since the date hereof.

INTROMMUNE THERAPEUTICS

THANK YOU

Contact us for more information and partnering opportunities

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Additional OMEGA Clinical Study Details

OMEGA Study Dosing Schema Overview & Evolution

Open
Oral Food Challenge

Screen participants for entry criteria
n=15

Up-dosing steps

Short-Term
Safety Assessment

Determine starting dose and safety of up-dosing protocol
n=13

No maintenance dosing

Lack of significant AE signal enabled protocol amendment: Extension to long-term safety and efficacy

Open and DBPC
Oral Food Challenge

Entry open OFC transitioned to double-blind, placebo-controlled OFC to assess efficacy of treatment
n=17

Up-dosing steps

Up-dosing period shortened

Maintenance dosing

Maintenance dosing period added

DBPC Oral Food Challenge + Long-Term Safety Assessment

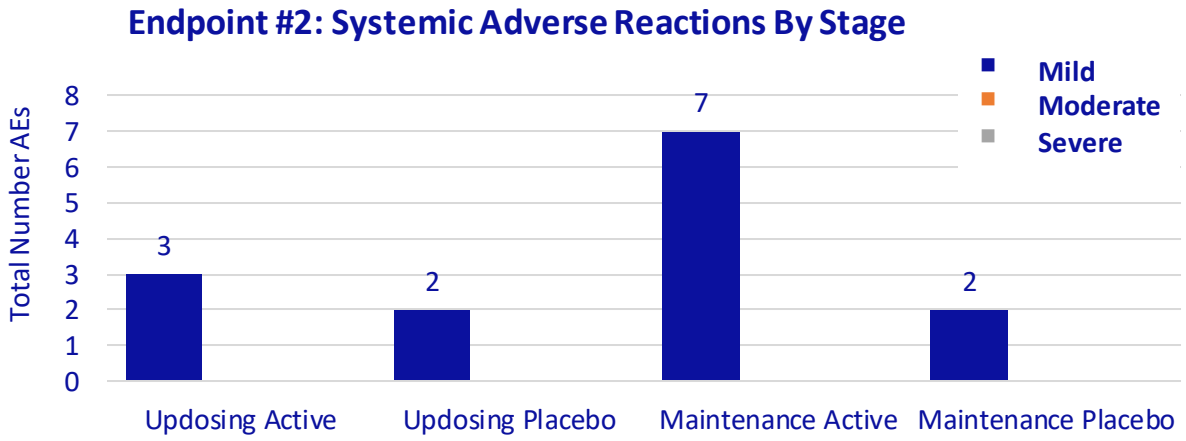
Added exit double-blind, placebo-controlled OFC
n=14

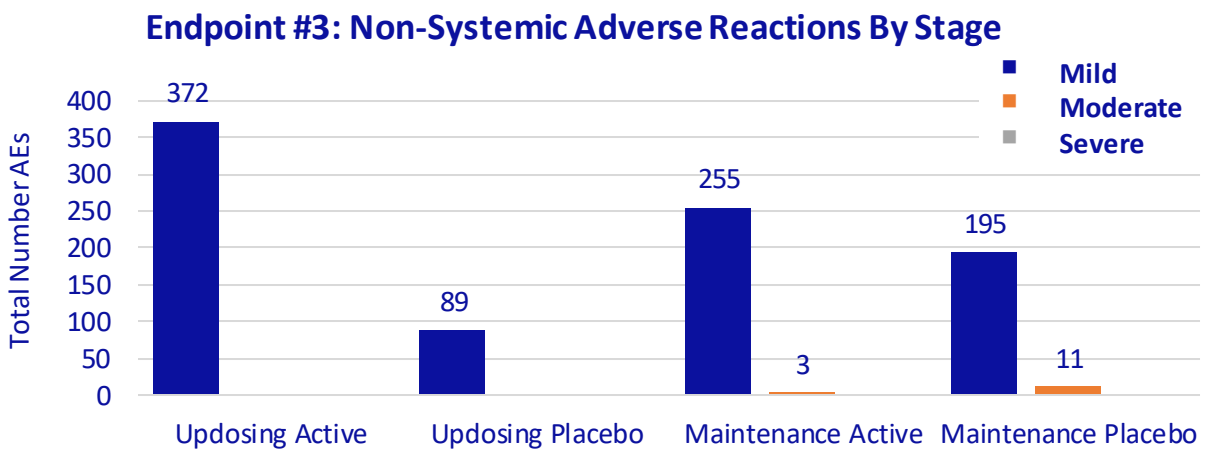
Trial Summary

OFC = Oral food challenge
DBPCOFC = Double-blind, placebo-controlled oral food challenge
Note: None of the 5 participants who exited the trial early did so due to study medication: 3 participants were removed for non-compliance with office visits, 1 participant was prescribed contra-indicated medication, 1 participant withdrew because of a change to their work schedule

Primary Objective Met - Safety

INT301 demonstrated safety across all treatment groups





- **Figure 1:** Mild systemic reactions experienced by 4.2% (n=1) of participants receiving INT301 and 25% (n=2) of placebo
- No (0) moderate and no (0) severe systemic reactions in active and placebo participants

- **Figure 2:** Mild non-systemic adverse reactions experienced by 87.5% (n=21 of 24) of participants treated with INT301 and 87.5% (n=7 of 8) of placebo*
- Moderate adverse reactions in 4.2% (n=1) of active and 12.5% (n=1) of placebo

Trial Summary

*Active treatment arm experienced more GI system AEs; # of placebo arm AEs substantially driven by a single participant

Note: The number of participants in the up-dosing stage is greater than the number of participants who continued on to maintenance. The maintenance stage is longer than the up-dosing stage

Secondary Objectives Met - AE Interventions, Adherence

Limited need for interventions related to AEs arising out of INT301

All participants on INT301 administered treatment for adverse events resolved and continued up-dosing

Drug Related Adverse Events Requiring Treatment						
Patient ID	**Preferred Term**	**Severity**	**Dose When AE Occurred/Max Dose**	**Relation to Drug**	**Treatment Given**	**Outcome**
100-062	Abdominal Pain	Mild	Dose 6/10 Maint.	Possible	Yes	Recovered/ Resolved
100-062	Abdominal Pain	Mild	Dose 7/10 Maint.	Possible	Yes	Recovered/ Resolved
100-066	Pharyngeal Swelling	Mild	Dose 8 /10 Maint.	Probable	Yes	Recovered/ Resolved
100-073	Lip Swelling	Mild	Dose 5/6	Probable	Yes	Recovered/ Resolved
100-073	Gingival Swelling	Mild	Dose 5/6	Possible	Yes	Recovered/ Resolved

Active Treatment Arm Reasons for Missed Doses	
Illness*	34
Misunderstood Instructions	24
Traveling	15
Forgot	8
Dispenser Issue	7
Unknown	3
Dentist Appt*	2
Other	2

Secondary Endpoints:

- **Number of Participants** requiring treatment for systemic reactions to INT301 or placebo = **0**
- **Number of AEs** requiring treatment for systemic reaction related to INT301 or placebo = **0**
- **INT301 Adherence:** Participants on treatment brushed their teeth with INT301 97% of days
- **Non-systemic, Mild AEs Requiring Treatment:** 12.5% (n=3) of active participants experienced a total of 5 possibly or probably drug related, non-systemic, mild AEs requiring treatment

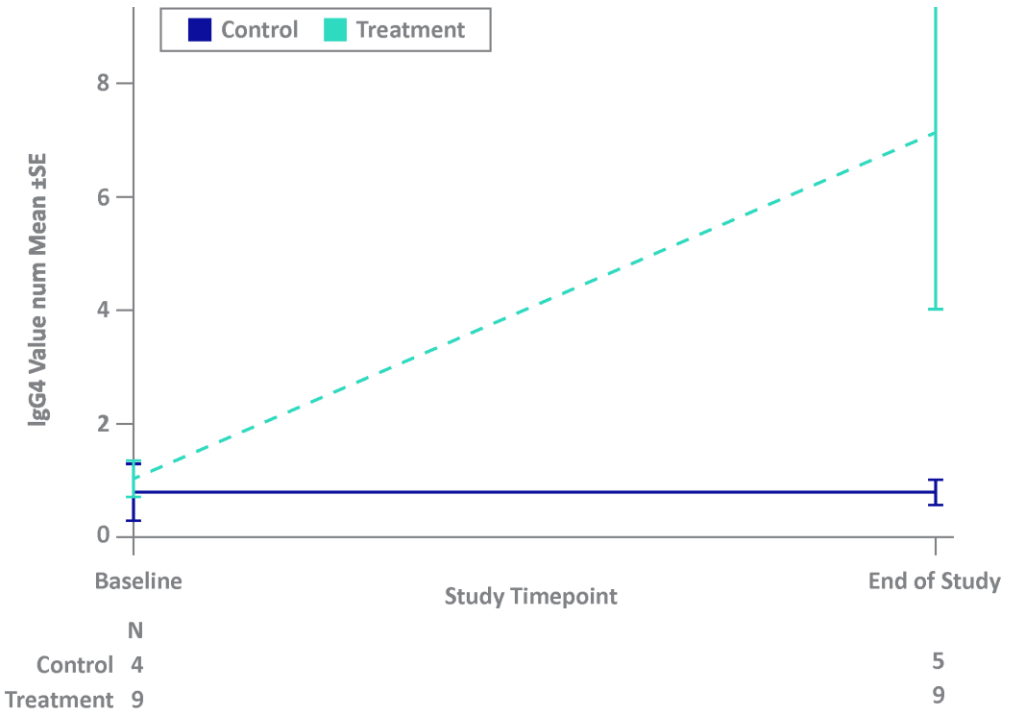
Trial Summary

*Protocol required reason to skip brushing

Exploratory Objective: Change in sIgG4

Impact on sIgG4 across treatment participants consistent with immune response to treatment

Long-term Safety Group



Key Findings

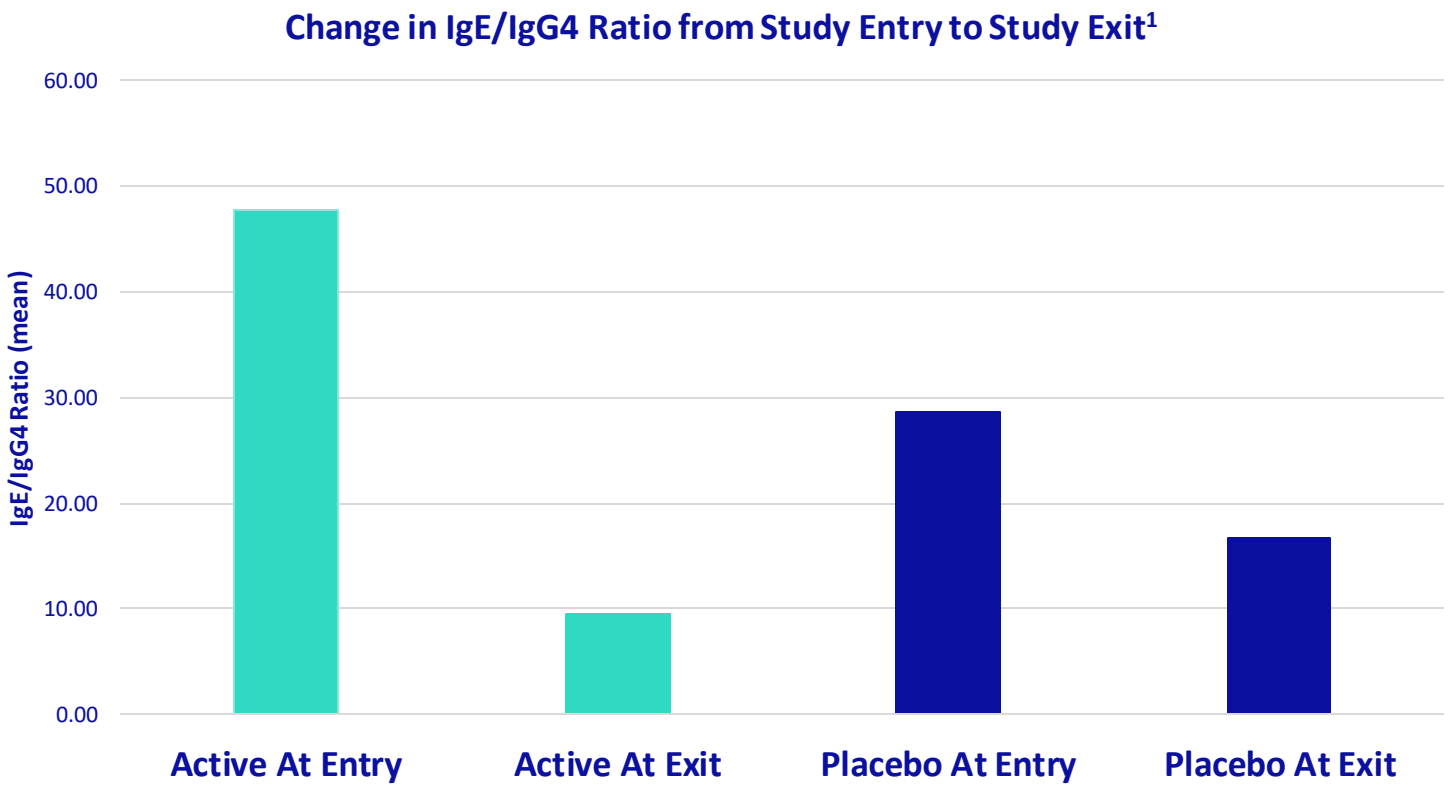
- Active participants demonstrated a significant change in sIgG4 levels relative to control **(p=.046)**
- Studies support the production of blocking antibodies, such as sIgG4 as one of the key mechanisms of immunotherapy[1]
- During immunotherapy, serum levels of sIgG4 have been shown to increase in a time and dose dependent manner

Trial Summary

1. Akdis CA, Akdis M. Mechanisms of allergen-specific immunotherapy and immune tolerance to allergens. *World Allergy Organ J*. 2015;8(1):17.

Exploratory Objective: Change in IgE / IgG4 Ratio

Decrease in IgE/IgG4 ratio over study period is consistent with an immune response to treatment



Key Findings

- Compared study entry IgE/IgG4 and study exit IgE/IgG4 among treatment participants
- Decrease in the IgE/IgG4 ratio in active participants (represented by the green bars in the graph) represent an immunologic response to treatment with INT301
- IgE/IgG4 ratio has been described as the immunological variable with the greatest size effect value, as compared to changes in sIgE or sIgG4 levels alone[2]

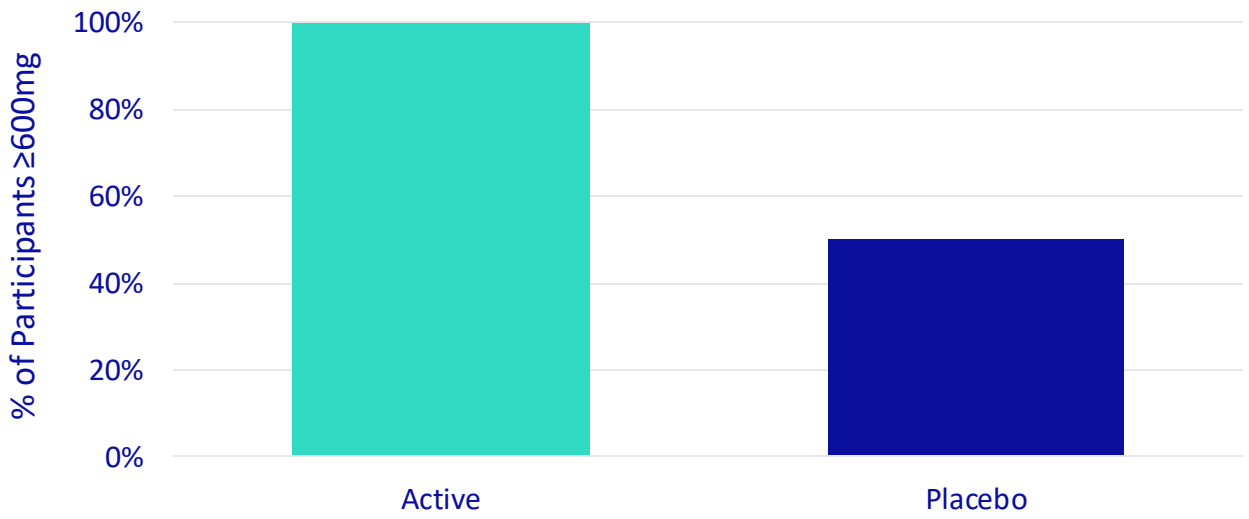
Trial Summary

1. Berger W. A Randomized Placebo-Controlled Phase 1 Safety Study of OMIT in Adults with Peanut Allergy [ACAAI Annual Meeting Abstract # LB011]. Ann Allergy Asthma Immunol 131 (2023) S230-S231.
2. Nikolov G, Todordova Y, Emilova R, Hristova D, Nikolova M, Petrunov B. Allergen-Specific IgE and IgG4 as Biomarkers for Immunologic Changes during Subcutaneous Allergen Immunotherapy. *Antibodies (Basel)*. 2021;10(4):49.

Exploratory Objective: Response to Food Challenges

100% of active treatment arm with entry DBPCOFC passed exit DBPCOFC at 600mg

Percent of Participants Who Had DBPCOFC At Both Entry and Exit Who Tolerated ≥600mg Peanut Protein at End of Study



Key Findings

- Participants who performed DBPCOFCs at entry: 100% of active (n=3 of 3) passed exit food challenge at 600mg (1043mg cumulative) and 50% of placebo (n=1 of 2) passed exit food challenges*
  - The placebo patient who passed the OFC had undetectable levels of Ara h 1, Ara h 2, Ara h 3, Ara h 6, and high levels of Ara h 8 and Ara h 9, consistent with oral allergy syndrome and tolerance to ingestion of peanut protein
- Additional analyses performed with biomarkers to evaluate signal due to the limited number of entry DBPCOFC

Trial Summary

DBPCOFC = Double-blind, placebo-controlled oral food challenge
*Based on preliminary interactions with the FDA, we believe the INT301 efficacy target for passing the exit OFC is ≥300mg