



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

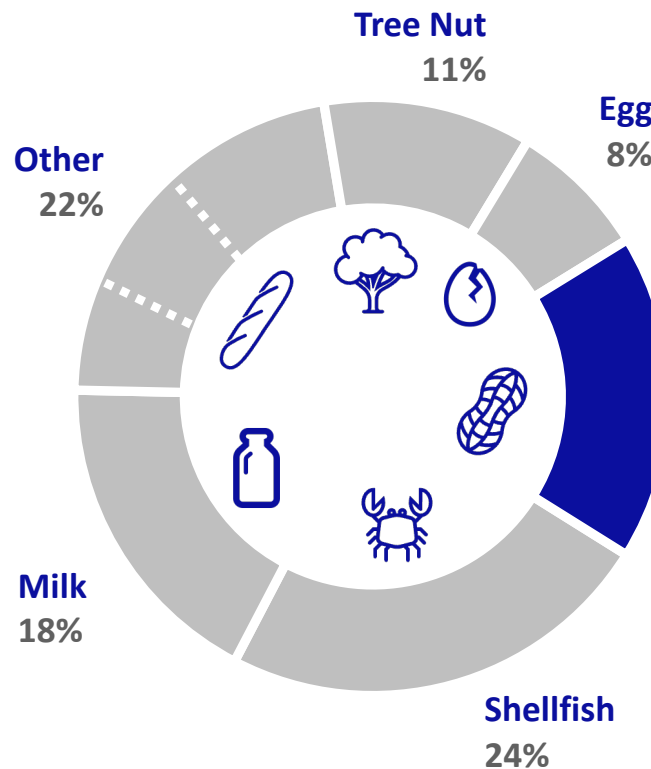
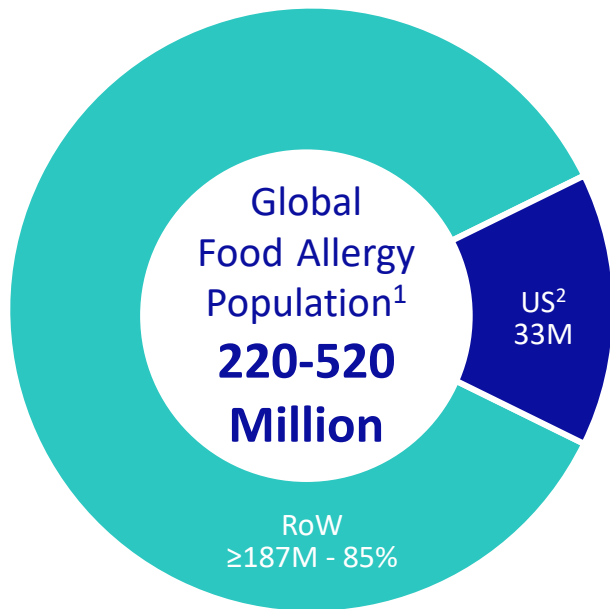
- **Multi-billion \$ market:** First application targets peanut allergies; ~\$7B TAM in U.S. alone
- **Opportunity with reduced risk and high expected ROI:** Recently released clinical trial results positive & provide clear direction for Phase 2 pediatric trial; strong IP portfolio
- **Minimal competition:** 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



Peanut³
18%

Peanut Allergy

\$7.4 Billion

TAM for U.S. market only⁴

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. Intromune Estimate

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 food¹



FEAR

92%

of parents feel fearful for their child's safety because of food allergies²



SOCIAL EXCLUSION

5 in 10

families with food allergies skip out on important school functions²



DISRUPTION

44%

of parents had to make a career change to care for their child with food allergies²



COST

\$25 Billion

spent annually by U.S. families caring for children with food allergies¹

*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

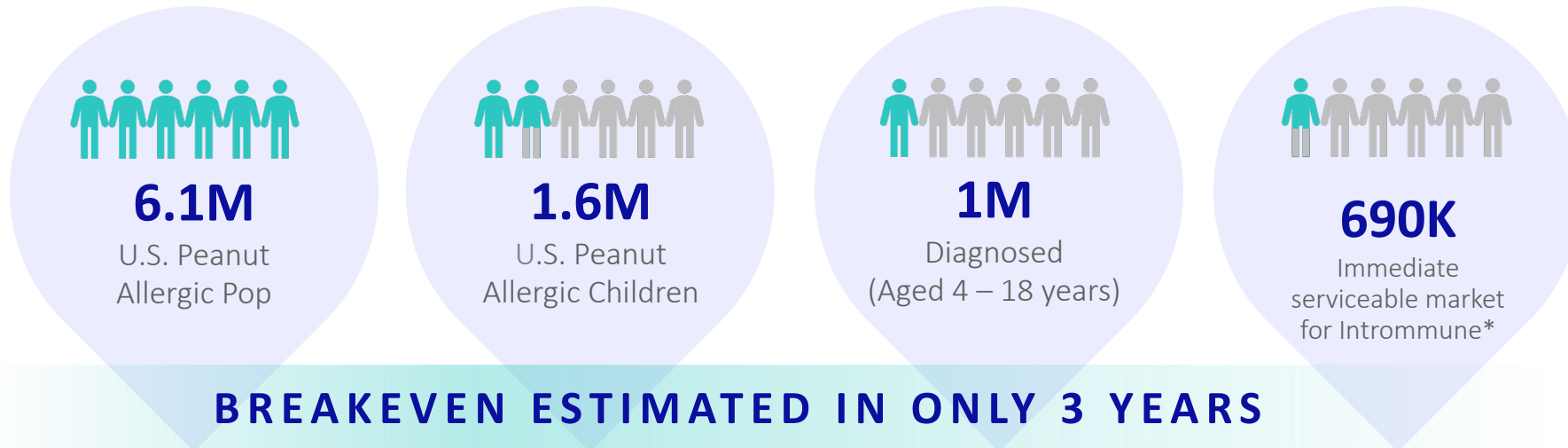
Food Allergies Represent a Multi-Billion Dollar Opportunity



PEANUT ALLERGY OPPORTUNITY



LARGE & GROWING UNMET NEED



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-threatening²
- 14% use of epinephrine reported in one Phase 3 pivotal trial²
- >35% experienced moderate treatment-related adverse events³

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

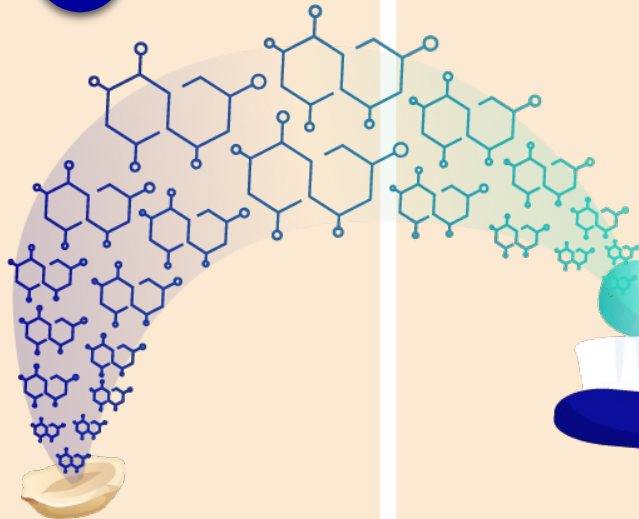
3. Brown KR, Baker J, Vereda A, et al. Safety of peanut (Arachis hypogaea) allergen powder-dnfp in children and teenagers with peanut allergy: Pooled summary of phase 3 and extension trials. *J Allergy Clin Immunol.* 2022;149(6):2043-2052.e9. doi:10.1016/j.jaci.2021.12.780. * Maximum severity of moderate (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



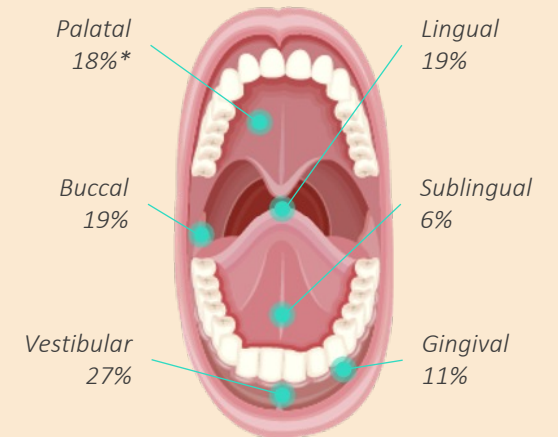
API stabilized & embedded
in functional toothpaste
in metered-dose dispenser

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

How Oral Mucosal Immunotherapy (OMIT) Works

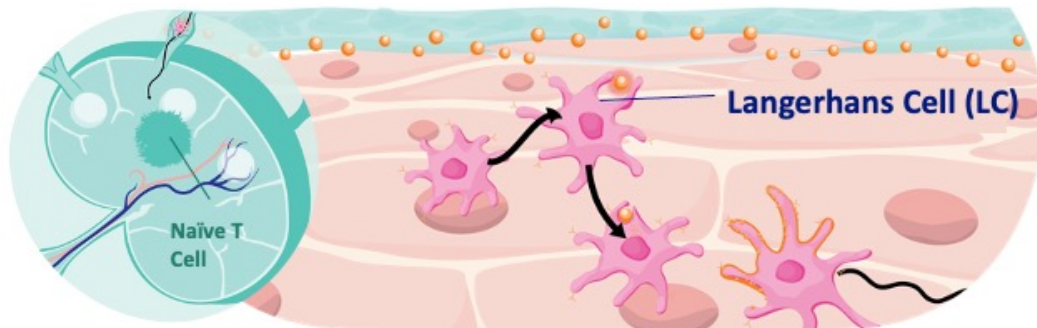
1

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



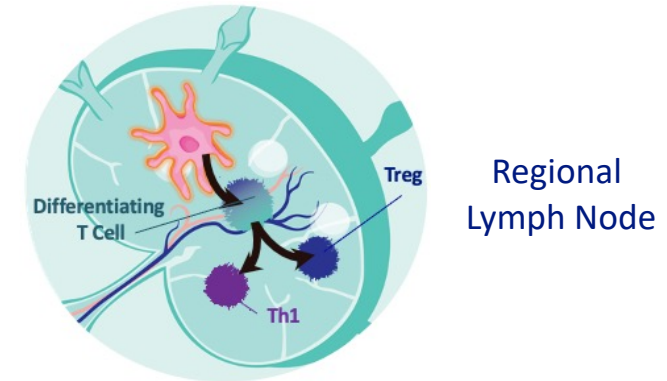
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Langerhans cells pull allergenic protein into the lymph system



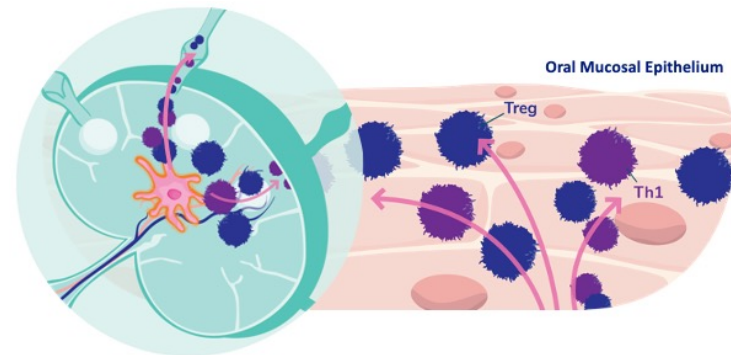
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Langerhans cells trigger the reeducation of immune system

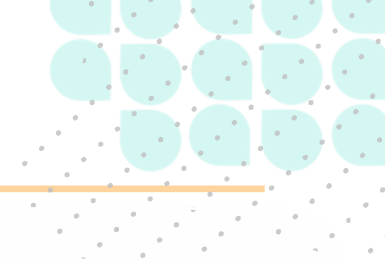


4

Differentiated T cells decrease the allergic response



Competitor Analysis



	OMIT	OIT	EPIT	Injection	INT301 Commercial Benefits
Dosing/ Administration	★★★★★	★★☆☆*	★★★☆☆	★★☆☆*	<ul style="list-style-type: none"> 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	★★★★★	★★☆☆*	★★★★☆	★★★★☆	<ul style="list-style-type: none"> 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	★★★★★	★★★★☆	★★☆☆*	★★★★☆	<ul style="list-style-type: none"> Unsurpassed efficacy gives patients/caregivers and HCPs confidence
Adherence/ Tolerance	★★★★★	★★☆☆*	★★★☆☆	★★☆☆*	<ul style="list-style-type: none"> 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

Recent Food Allergy News

Palforzia

(Nestlé & Aimmune)



Points of Interest

- Palforzia requires a 4-5 hour first office visit to accommodate 5 doses and mandatory wait between doses
- Launched during COVID, making initiation difficult
- Because OIT is swallowed, there is a high rate of anaphylaxis/epinephrine use and a very high rate of gastrointestinal pain

ADP101

(Alladapt)

ClinicalTrials.gov Identifier: NCT05243719

Recruitment Status ⓘ : Terminated (Sponsor decision)
First Posted ⓘ : February 17, 2022
Last Update Posted ⓘ : March 26, 2024

Points of Interest

- ADP101 is OIT, but has the complications of 15 food allergens, creating significant regulatory and manufacturing challenges
- Consistent feedback from KOLs was that this program was going to have significant developmental risks

Xolair

(Novartis & Genentech)



Points of Interest

- Brings attention to the food allergy space
- Injection given every 2-4 weeks
- Only blocks IgE and does not disease-modify like allergy immunotherapy
- Expensive (\$36,000-\$140,000 per year)
- Intromune's OMIT would be used concomitantly with Xolair
- Interest from Big Pharma and manufacturers who are seeking partnership with Intromune

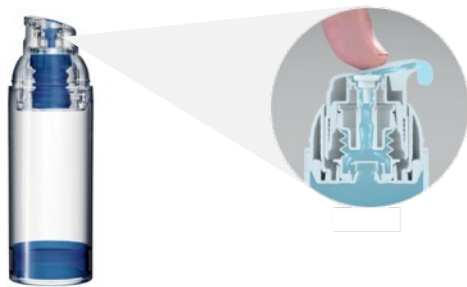
Development Substantially Advanced for Peanut Allergy Solution



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

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

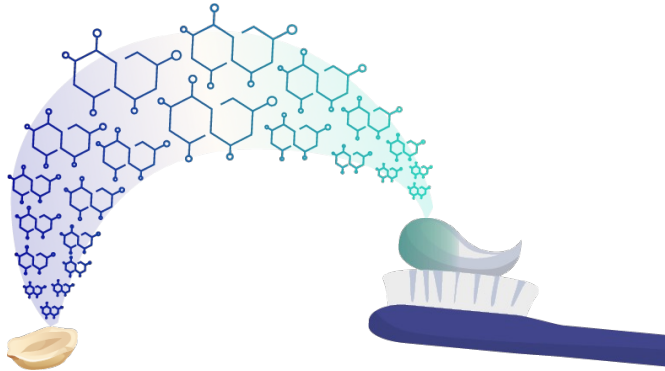
- Additional innovation
- New filings - dosing, CMC & design
- Regulatory extension
- Unique biologic – no generic pathway available

OMEGA Study



What is INT301?

Intrimmune'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

Highlights from OMEGA Phase 1 / 2 Clinical Trial Results



Met primary and secondary endpoints, with indications of efficacy



Safety

Demonstrated exemplary safety: No moderate nor 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% of those treated with toothpaste consistently tolerated the pre-specified protocol highest dose*



Dropout

0% product-related participant dropout rate

Additional OMEGA Clinical Study Details

Conclusion: OMEGA Study¹ 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**

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



TV



"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

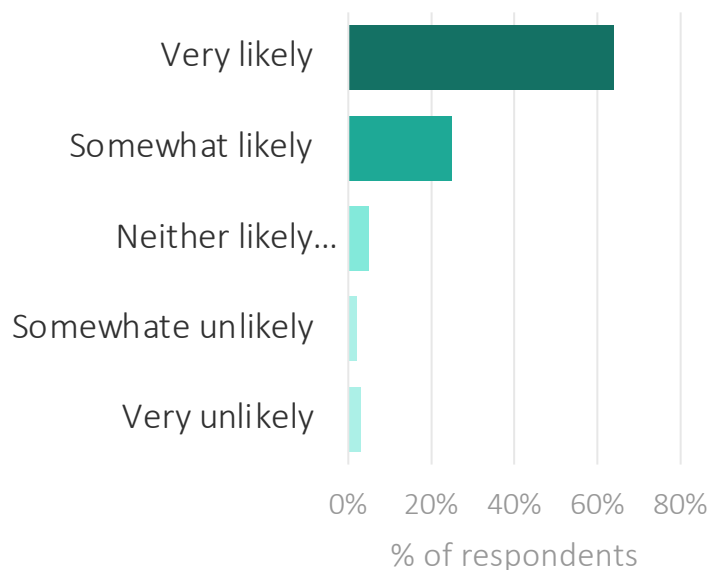


Strong HCP & Consumer Interest in Intrimmune's OMIT Solution



Patients

Likelihood to Try Immunotherapy-based Toothpaste for Peanut Allergy



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, FAAAAI, FAAAAI,

Executive Medical Director, ACAAI
Pediatric Allergist, Gundersen Health System



*"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, FAAAAI, FAAAAI

Clinical Professor, Medical College of Georgia at Augusta



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

~6000 Allergists¹

Prescribe off-label
“home-brew” food
allergy solutions

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

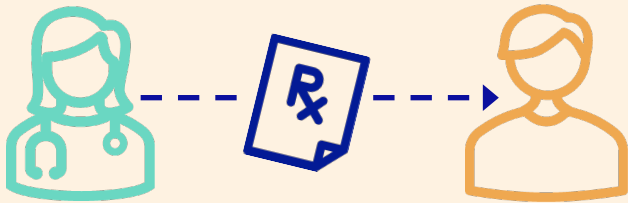
 = ~200 allergists/immunologists

Competitively Differentiated Business Model Will Drive HCP Support

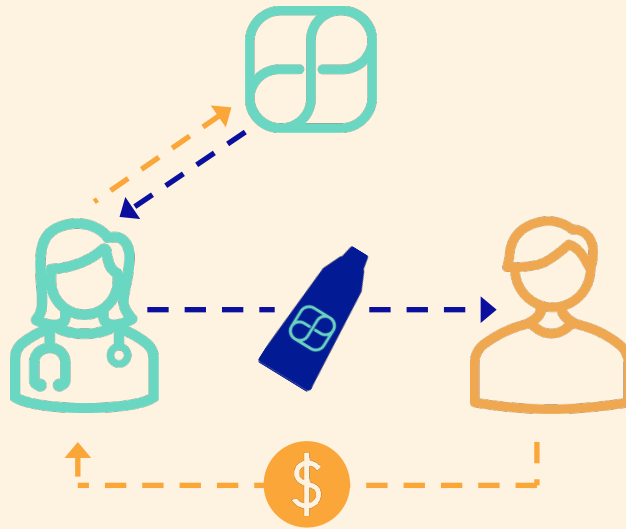


Buy-and-bill model during initiation/up-dosing, transitioning to Rx mail order for maintenance

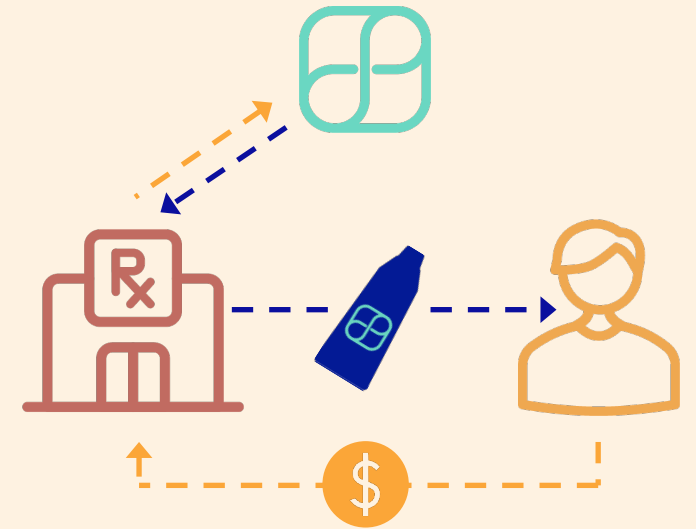
Food allergy confirmed via test*; doctor prescribes Intromune INT301



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



Transitions to prescription mail order pharmacy for maintenance



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



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

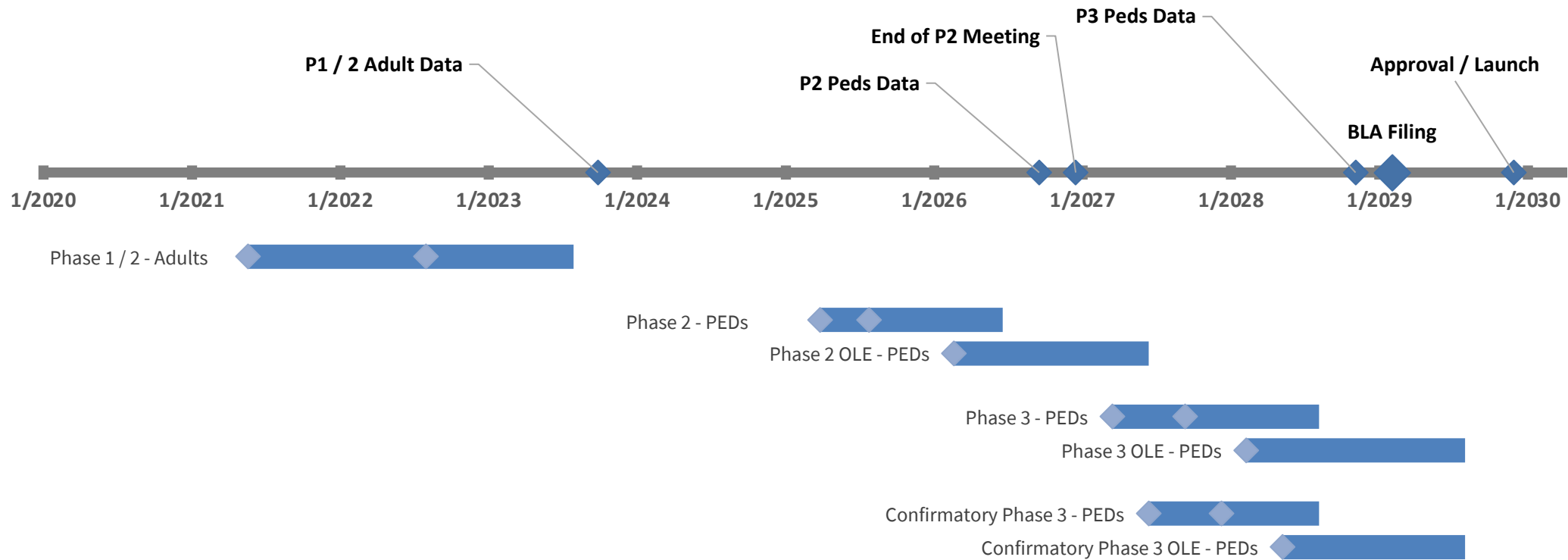


Clinical Roadmap (INT301)

Series B

\$38M

Intrommune Therapeutics INT301 Clinical Timeline



Experienced Leadership Team

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



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 subjects¹ 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 subjects² 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

The information regarding the proposed private placement offering by Intrommune Therapeutics is being provided to you on a confidential basis only and should not be disclosed to anyone other than your professional advisers on a confidential basis for purposes related to your interest in the company. This information should not be divulged, reproduced or disseminated without our consent.

Only qualified “accredited investors” as defined in Regulation D under the Securities Act of 1933, as amended will be permitted to participate in the proposed offering. Additional suitability requirements may apply.

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THANK YOU

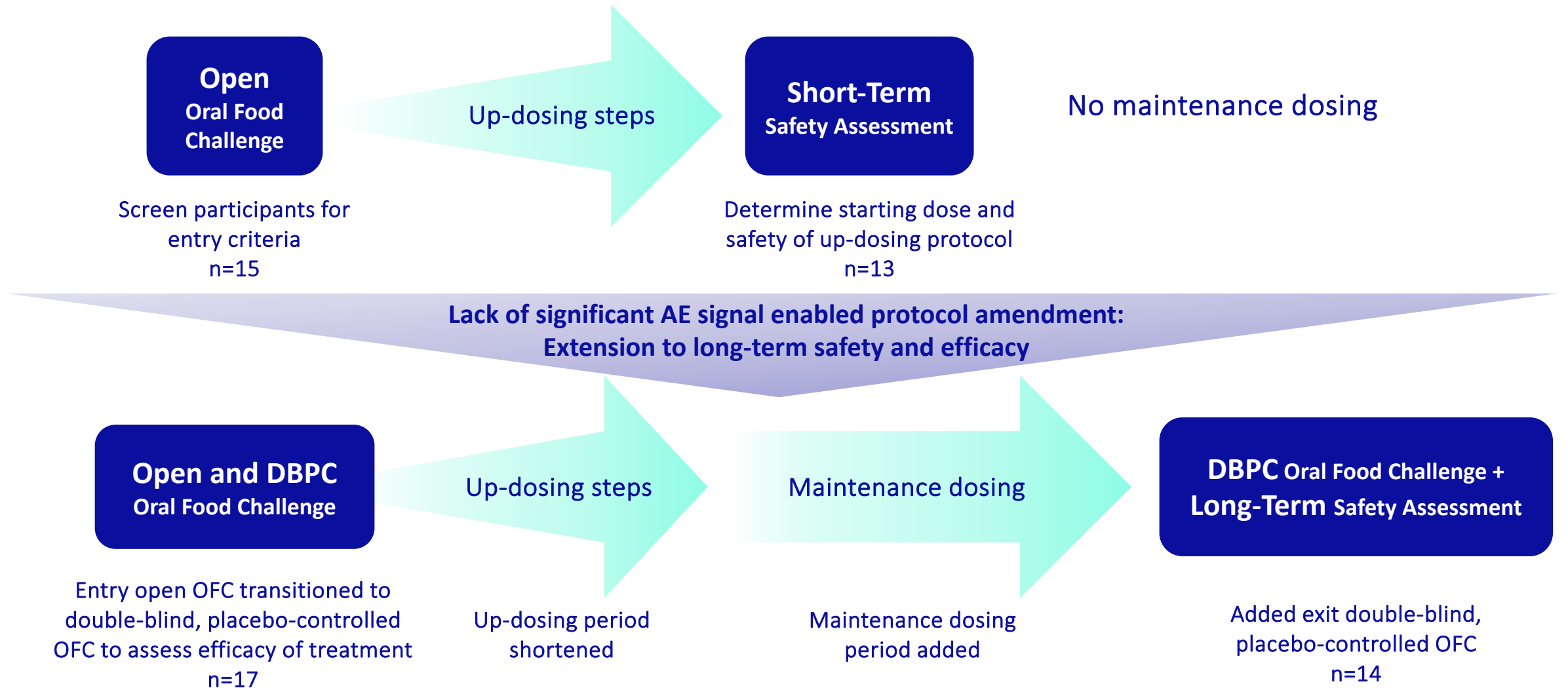
Contact us for more information
and partnering opportunities

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Additional OMEGA Clinical Study Details

OMEGA Study Dosing Schema Overview & Evolution



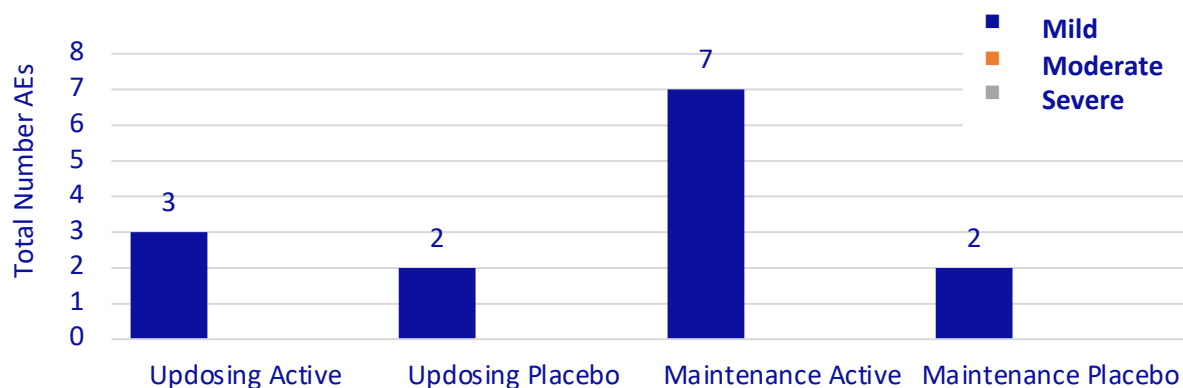
Trial Summary

Primary Objective Met - Safety



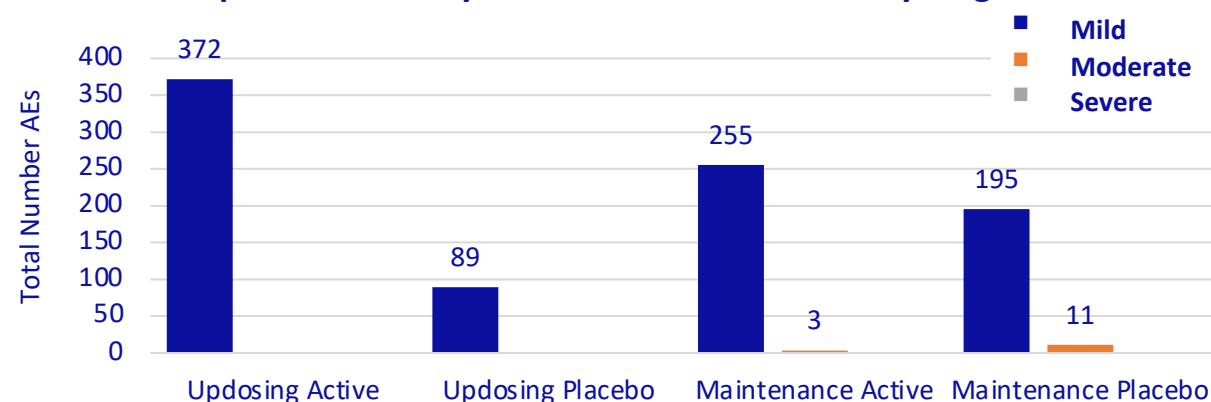
INT301 demonstrated safety across all treatment groups

Endpoint #2: Systemic Adverse Reactions By Stage



- **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

Endpoint #3: Non-Systemic Adverse Reactions By Stage



- **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

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

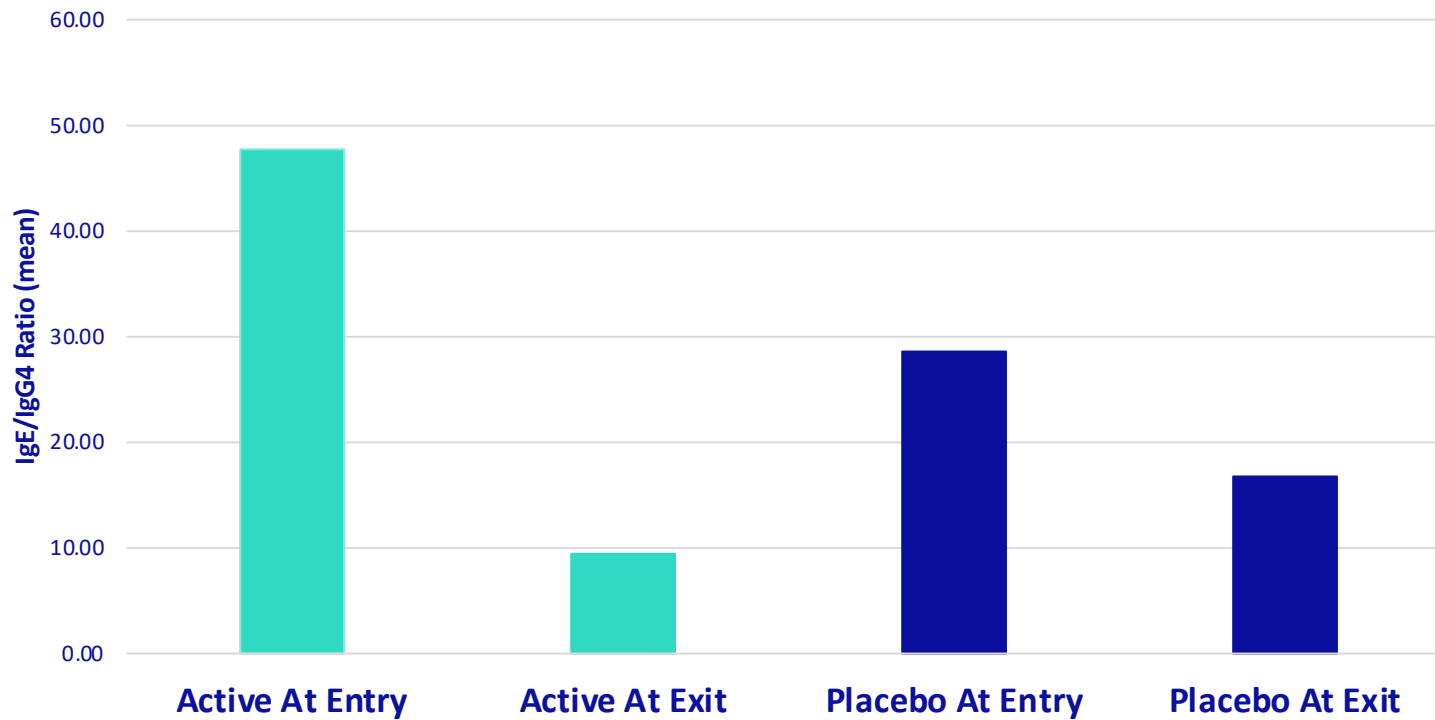
Trial Summary

Exploratory Objective: Change in IgE / IgG4 Ratio



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

Change in IgE/IgG4 Ratio from Study Entry to Study Exit¹



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 alone²

Trial Summary

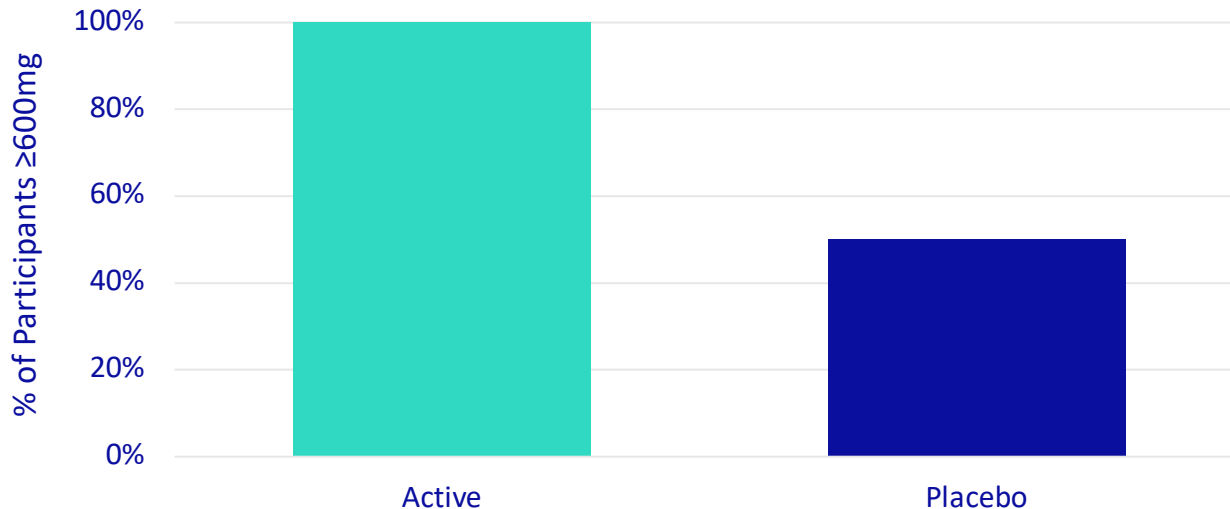
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2. Nikolov G, Todordova Y, Emilova R, Hristova D, Nikolova M, Petrunov B. Allergen-Specific IgE and IgG4 as Biomarkers for Immunologic Changes during Subcutaneous Allergen Immunotherapy. *Antibodies (Basel)*. 2021;10(4):49.

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 \geq 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