



Transforming Food Allergy Treatment –
Helping People With Food Allergies Live Better

Executive Summary



Problem

FOOD ALLERGY MARKET CONTINUES TO BE 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

INTROMMUNE PREPARED TO TAKE ON FOOD ALLERGIES – LOCALIZED ADMINISTRATION

- **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 and tree nut allergies; ~\$14 B TAM in U.S.
- **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; interim decision points
- **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

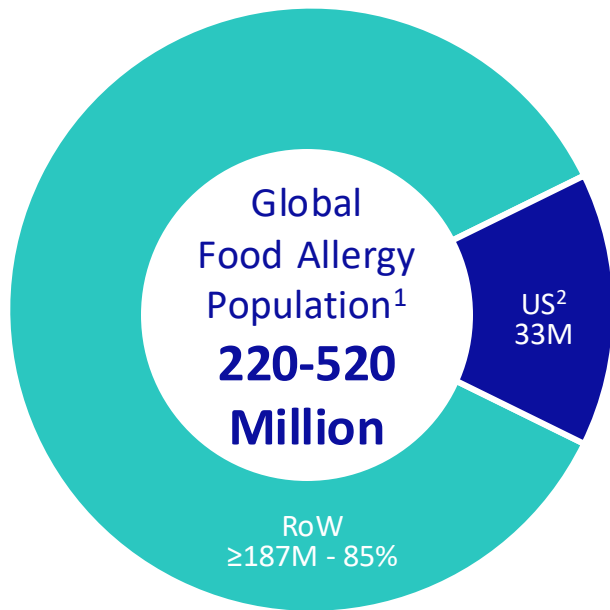
Our Thesis:

People will use food allergy treatments that are convenient and not disruptive to everyday life

Food Allergies Impact Millions Globally



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



Peanut / Tree Nut Allergy

\$14 Billion

TAM for US market⁴

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. FAACT Food Allergy & Anaphylaxis Connection Team www.foodallergyawareness.org/food-allergy-and-anaphylaxis/food-allergens/the-top-9-food-allergens/

4. Intromune Estimate – \$10,680 price at January 2020 approval. Price on September 10, 2023 is \$14,880/year per drugs.com

Food Allergies Represent a Multi-Billion Dollar Opportunity



PEANUT / TREE NUT ALLERGY OPPORTUNITY

TAM

\$14 Billion*
(US market only)

GROWTH

Market forecasted to grow
1,700-fold
from 2017 to 2027¹

INSURANCE COVERAGE

Yes

OIT PRICE/YEAR PER PATIENT

\$10,680²

LARGE & GROWING UNMET NEED



9.8M

U.S. Peanut /
Tree Nut
Allergic Pop



2.3M

U.S. Peanut /
Tree Nut Allergic
Children



1.5M

Diagnosed
(Aged 4 – 18 years)



1.1M

Child Immediate
serviceable market
for Intromune*

BREAKEVEN ESTIMATED IN ONLY 3 YEARS POST LAUNCH

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

Continues to Be No Cure & Limited Solutions to Food Allergies

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

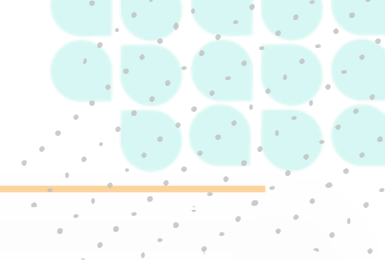
- ~9.5% experienced anaphylaxis, which may be life-threatening²
- 14% use of epinephrine reported in one Phase 3 pivotal trial²
- >35% experienced moderate treatment-related adverse events³



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

Competitor Analysis

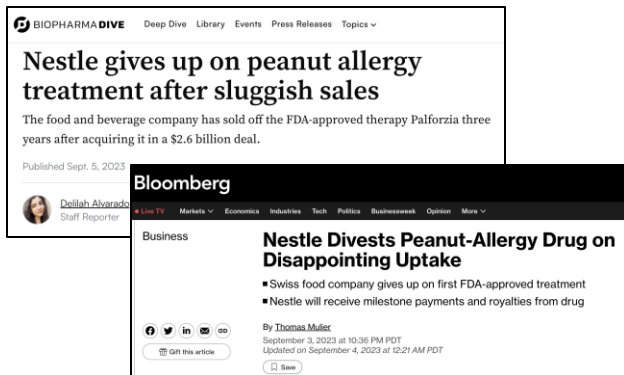


| |  |     |   |   | |
|---------------------------|---|---|---|---|--|
| | OMIT | OIT ¹ | EPIT | Injection ² | OMIT Commercial Benefits |
| Dosing/ Administration | ★★★★★ | ★★☆☆☆ | ★★★☆☆ | ★★☆☆☆ | <ul style="list-style-type: none"> No need for 4-5 hour office visit at first dose Half the number of up-dosing 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 OMIT not being swallowed |
| Efficacy | ★★★★★ | ★★★★☆ | ★★★☆☆ | ★★★★☆ | <ul style="list-style-type: none"> Expected efficacy will provide patients/caregivers and HCPs confidence Disease modifying |
| 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 will encourage adherence Pain free Power toothbrush gamification and bluetooth capabilities |

Competitive Analysis: Learnings & Market Impact

Palforzia

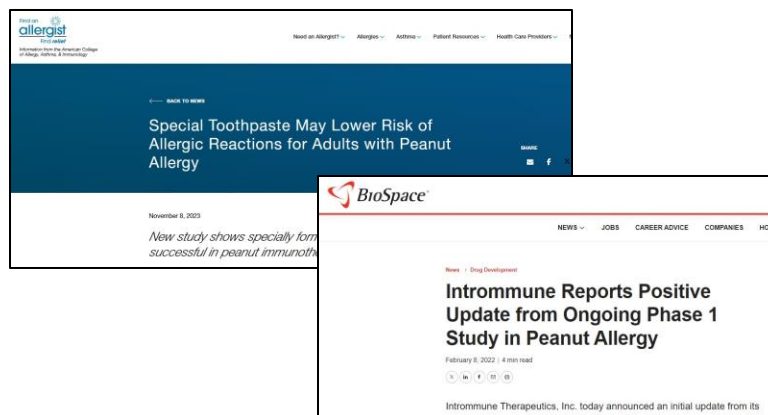
(Nestlé & Aimmune)



- Palforzia has a challenging up dosing schedule with a high risk of severe AEs — Intrommune’s novel toothpaste platform addresses adherence and safety from the start
- Parents of children with food allergies are driving the multi-billion-dollar industry so Intrommune is determined to prove itself in the pediatric space with the next rounds of funding

INT302

(Intrommune)



- Intrommune committed to a focused, step-wise approach, first tackling peanut / tree nut allergies, which remains a \$14 billion market primed for the taking
- Intrommune and its esteemed KOLs understand and rightly anticipated the pitfalls of OIT—and conversely the continued massive potential for OMIT
- Xolair is not disease modifying – expectation is that patients on Xolair will transition to OMIT

Xolair

(Novartis & Genentech)

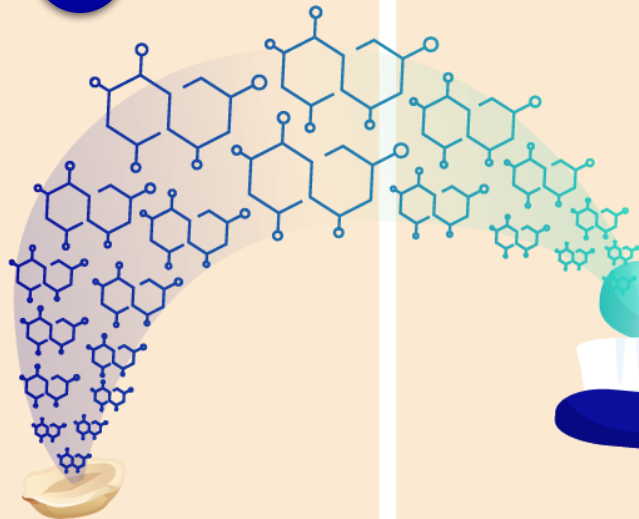


- Although this moves the food allergy space in the right direction, those with food allergies do not view Xolair as a long-term solution and continue to seek out new treatments
- Cost of Xolair remains a huge barrier to uptake, leaving many to feel defeated
- Positive attention to the food allergy space has reignited discussions between Intrommune and Big Pharma and other manufacturers

Our Solution: Novel Technology Simplifying Allergy Immunotherapy

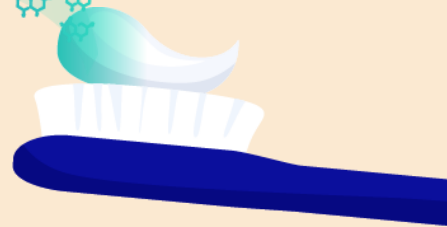
Food allergy desensitization transformed into easy-to-use platform via proprietary technology: Oral Mucosal Immunotherapy (OMIT)

1



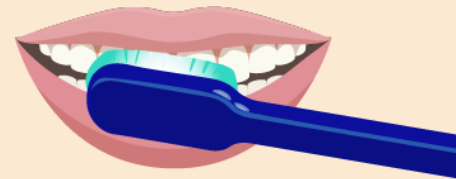
Allergenic proteins (API)
mechanically & chemically
processed via proprietary methods

2



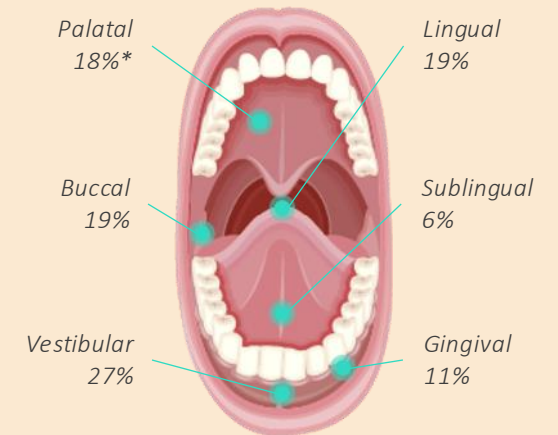
API stabilized & embedded
in functional toothpaste
in metered-dose dispenser

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

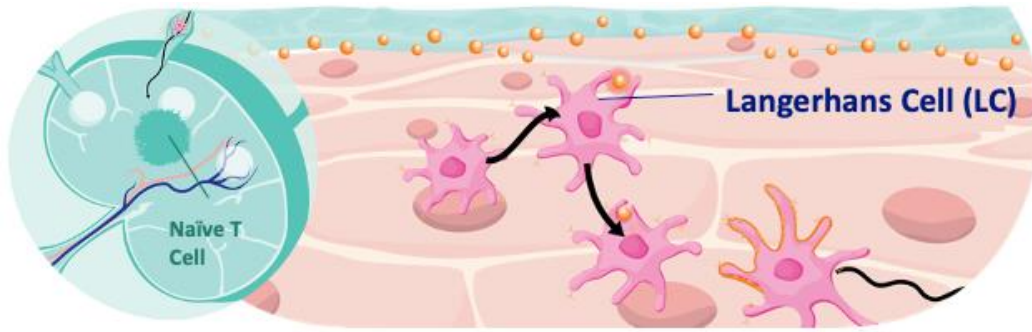
1

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



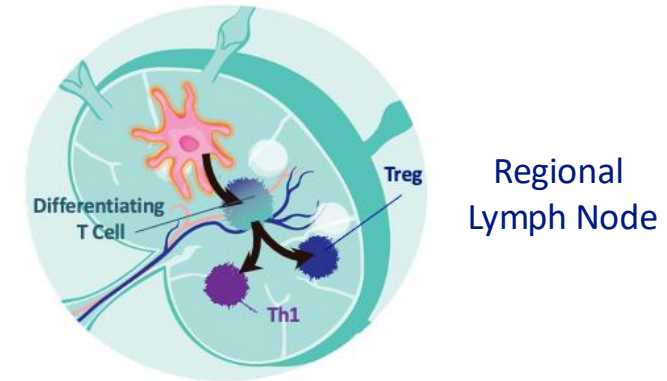
2

Langerhans cells pull allergenic protein into the lymph system



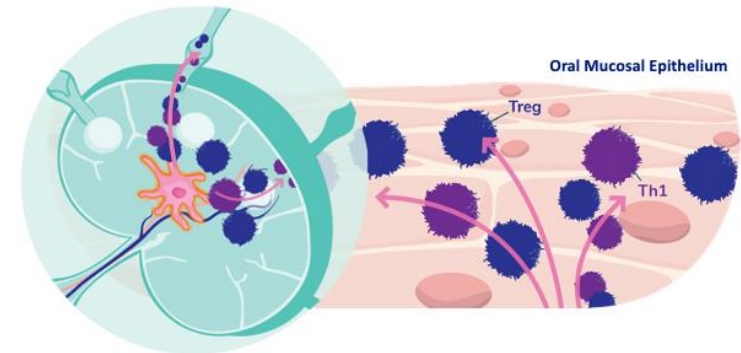
3

Langerhans cells trigger the reeducation of immune system



4

Differentiated T cells decrease the allergic response



Development Substantially Advanced for Food Allergy Solution



Significant progress made to advance and de-risk development

Product Development

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

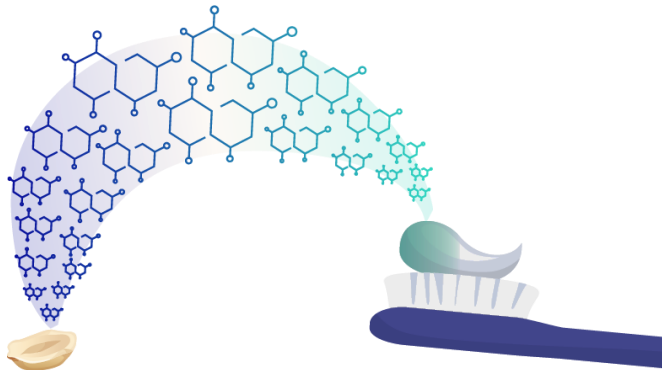
- Phase 1 / 2 DBPC OMEGA Trial* in adults complete
 - Met all primary and secondary safety endpoints
 - Exploratory objective provided indications of efficacy
- Due to impressive safety profile to date, FDA greenlit pediatric Phase 2 study prior to completion of our adult Phase 1 / 2 study

OMEGA Study



What is INT301?

Intromune'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
- Excluded 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 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:
 - ✓ 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
 - ✓ 22% of OIT patients drop out within first year and as many as 50% within 3 years

Additional OMEGA Clinical Study Details

Top-Line Results Presented at ACAAI & AAAAI

Generated >140 pieces of news coverage & on >900 TV/Cable/Radio shows in 36 hours

Late-Breaking ACAAI Abstract

- Oral presentation given Nov. 11, 2023 at American College of Allergy, Asthma and Immunology Scientific Meeting



- Published in 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

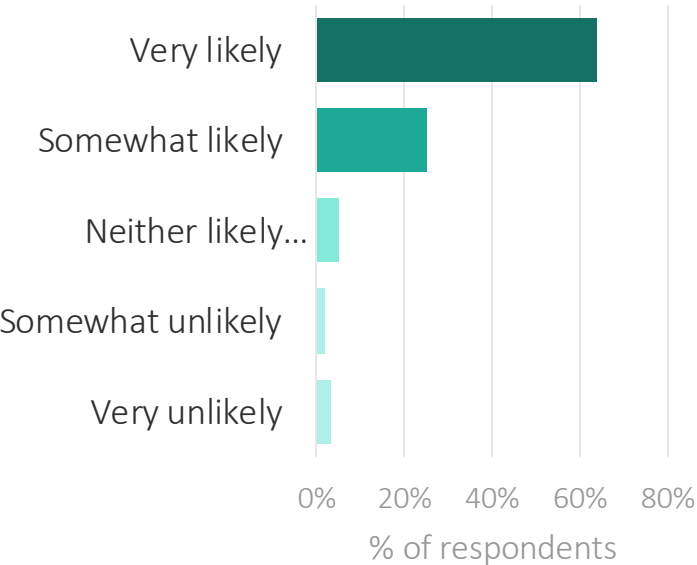


Patients



Healthcare Professionals

Likelihood to Try Immunotherapy-based Toothpaste for Peanut Allergy



*"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



THE JOURNAL OF
**Allergy AND Clinical
Immunology**

The Journal of Allergy and Clinical Immunology:
In Practice

Key considerations in next generation of food AIT

The flowchart shows the progression from **selection** to **Optimized protocol** to **Improved outcomes**. The **Optimized protocol** includes **Modified allergens** and **Adjustments to treatment**. The **Improved outcomes** include **Potential for tolerance** and **Alternative routes of delivery**. The final goal is to **Enhance safety, efficacy, and quality of life**.

Key considerations in next generation of food AIT. Studies have sought to improve patient selection, provide tiered care, and identify the ideal protocol by investigating allergens, adjuncts, and alternative routes of delivery. The overall goal of improving safety, efficacy, and life and striving for tolerance.

| Study | Population | Treatment duration | Primary end point |
|-------|--|--------------------|--|
| III | 1-55 yr with peanut allergy and ≥2 other food allergy (wheat, milk, soy, barley, rice, buckwheat, hazelnut, peanut, cashew, pistachio, almond, walnut, sesame) | 30-36 wk | ≥900 mg single dose of peanut without dose-limiting symptoms |
| IIIb | 6-23 yr with allergy to >3 foods (peanut, milk, egg, wheat, soy, barley, rice, buckwheat, hazelnut, peanut, cashew, pistachio, almond, walnut, sesame) | 52 wk | Time-to-maintenance (≥500 mg) during optimized OIT protocol |
| II | 4-55 yr with peanut and 1-2 other food allergens (milk, soy, wheat, rice, buckwheat, hazelnut, egg, walnut, sesame, soy, almond) | 44 wk | ≥1940 cumulative dose without dose-limiting symptoms to (1) peanut, 120 peanut and 211 other foods; (2) peanut and 2 other foods |
| II | 6-17 yr with peanut allergy | Up to 40 wk | ≥2040 mg cumulative dose of peanut |
| II | 4-50 yr with cow's milk allergy | 38 wk | ≥2040 mg cumulative dose of cow's milk |
| II | 4-17 yr with peanut allergy | 12 mo | ≥1940 mg cumulative dose of peanut |
| IIa | 1-37 yr with peanut allergy | 18 mo | ≥180 mg sustained unresponsiveness |
| IIb | 12-35 yr with peanut allergy | 7 wk, 23 wk | Number of participants with treatment-related adverse events Executive summary of the outcomes released: dose of peanut protein at DDPCC1 |
| II | 4-17 yr with peanut allergy | 52 mo | (1) If initial ED in <30 mg ED in <300 mg peanut (2) If initial ED in >30 mg ED in >300 mg peanut ED > 1000 mg at 12, 24, and 36 mo |
| III | 2-5 yr with peanut allergy; completed the FOTFOT study | 36 mo | |
| I | 4-65 yr with peanut allergy | 2 wk | Incidence of local application-site reactions |

Abbreviations: ED, end point; FOTFOT, Food Oral Tolerance Food Oral Tolerance study.



IP covers all food allergens across multiple oral care formats, with 51 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
- 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

Experienced Leadership Team

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



Michael Nelson, JD
Chief Executive Officer



Michael Holfinger, PhD
Chief Technology Officer



William Berger, MD, MBA
Head of Medical Affairs



Ray Forslund
Head of Chemistry,
Manufacturing & Controls



Nandini Murthy
Head of Regulatory



Erick Berglund, PhD
Chief Science Officer



Christopher Schuster, MBA
Chief Financial Officer



Michelle Mantia
Controller



Miles McLennan
Head of Clinical Operations



Nicole Faris
Strategic Director, Medical
Affairs & Clinical Development



Sharon Chinthrajah, MD
Medical Advisor



Stuart Loesch
Commercial Advisor

Opportunity to Get in Early on Technology with High Expected ROI



Intromune offers attractive opportunity that targets an established, reimbursed market

- ✓ **Large, growing market** with established reimbursement – Peanut TAM of ~\$7B/Peanut-Tree Nut of ~\$14B in U.S.
- ✓ **Multiple applications & opportunities** enabled by unique immunotherapy platform technology
- ✓ **Minimal competition** - Hard to use peanut allergy immunotherapy and an injectable monoclonal antibody
- ✓ **OMIT highly differentiated** vs. current OIT solution, with expected safety, efficacy & adherence benefits:
 - Intromune's INT302 is best-in-class agent – 9 in 10 subjects¹ will try
 - 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

Disclosures



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Contact us for more information
and partnering opportunities

Michael Nelson, CEO
mnelson@intrommune.com
(+1) 917-885-9507