

alladapt

IMMUNOTHERAPEUTICS

Reimagining the treatment of food allergy to
transform patient lives

Corporate Presentation
January 2023



Developing the First Treatment for The Majority of Severe Food Allergies



A Serious Immunologic Disease

- 32m children and adults in the U.S. with 95% lack treatment options → standard of care: meticulous avoidance + epinephrine
- The only atopic disease without a single blockbuster intervention

ADP101: A Singular Therapy Simultaneously Targeting Allergens Associated with 90% of Severe Reactions

- A pharmaceutical-grade oral immunotherapeutic agent to mitigate risk of severe, life-threatening allergic reactions
- Designed to address limitations with current options: scalability, accessibility, reproducibility

Clinical Data Expected Q1 2023

- Phase 1/2 Harmony study fully enrolled with 73 pediatric and adult patients

Therapeutic Modality: An Established, Foundational Approach for Food Allergy

- Large body of evidence supports use of OIT
- Use in combination with biologics may further expand market opportunity

Patient-Centric Formulation; Scalable Manufacturing

- Phase 3 scale-up of robust, pharmaceutical-grade manufacturing and control processes underway

Strong IP Portfolio

- IP estate/clinical data licensed from Stanford University/Dr. Kari Nadeau

Financing History

- \$119m Series D led by Patient Square including AllerFund, Red Tree Venture Capital, West River Group, Novartis, and founding investor Gurnet Point Capital (June 2022)
- \$182m raised since inception

Senior Leadership Team and Board of Directors

Deep, diversified experience across biotech & allergic disease landscape



Ashley Dombkowski, PhD
Co-Founder and CEO



Dana McClintock, MD
Chief Medical Officer



Michael Holfinger, PhD
Chief Technical Officer



Glenn Reicin
Chief Financial Officer



Kari Nadeau, MD, PhD
Co-Founder



Stacey Seltzer
Gurnet Point Capital



Jim Momtazee
Patient Square Capital



George Montgomery
Retromer Therapeutics



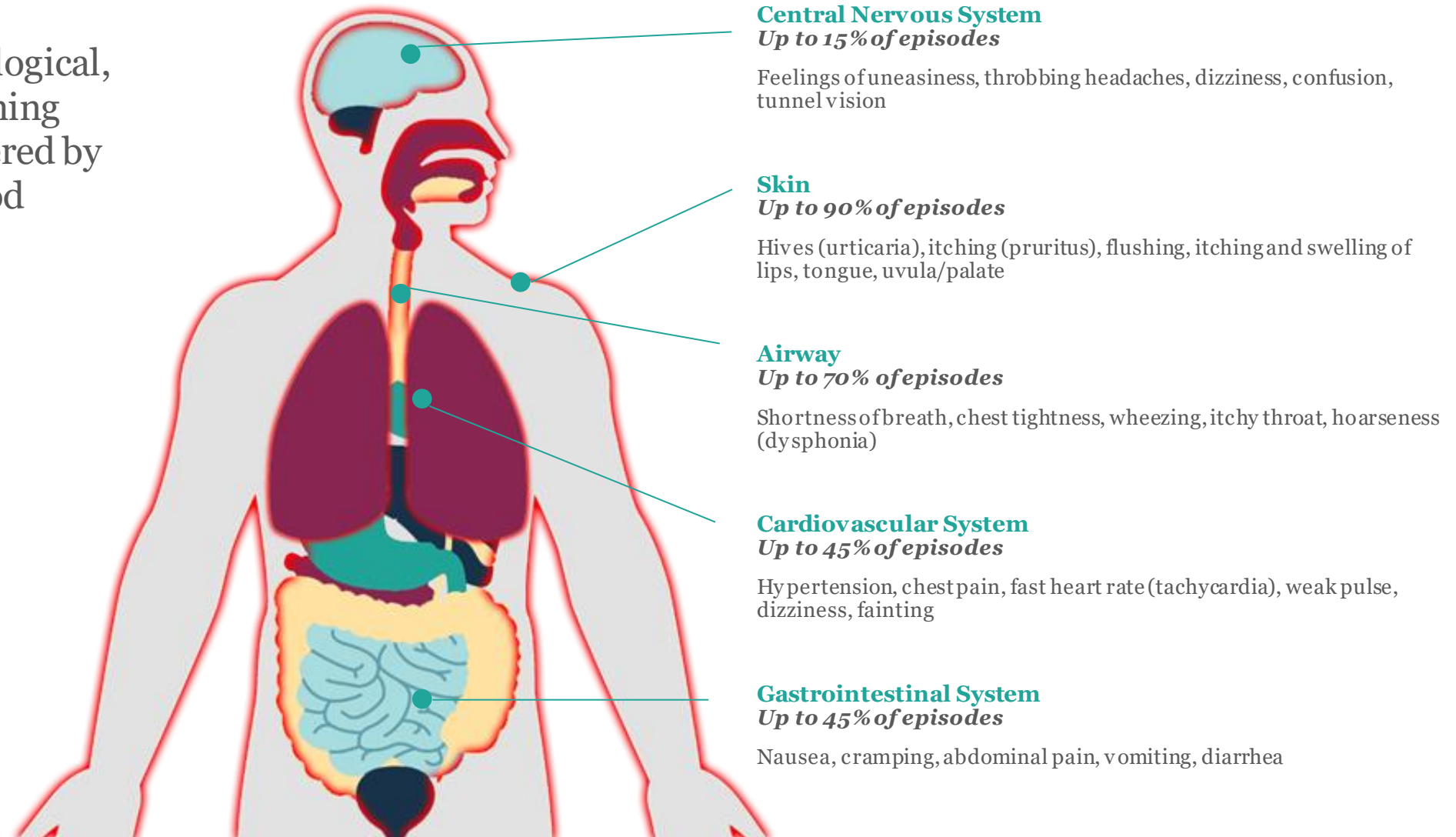
Travis Wilson
Gurnet Point Capital

Food Allergy Exposures Can Have Severe, Multi-System Impact

Accidental exposure can lead to anaphylaxis and to potentially life-threatening complications

Food Allergy is a pathological, potentially life-threatening immune reaction triggered by normally innocuous food protein antigens.

(Nature Reviews, 2016)



Constant, Meticulous Allergen Avoidance is an Unrealistic Standard of Care and Poses Significant Obstacles to Living a Normal Life

Urgent need for novel therapies that mitigate both clinical and psychological burden



Rapid and potentially fatal reactions often require immediate medication (e.g., epinephrine auto-injector) and **emergency medical care**



Allergen **avoidance diets are burdensome and difficult** to follow, particularly for non-peanut allergies that are less recognized or prevalent



Constant vigilance to avoid accidental exposure **contributes to high stress and anxiety** for patients and their relatives



Amplified psychological burden in restaurants, school, and social settings where food allergens are pervasive **can make patients feel isolated**

“You want their childhood memories to be happy and for social experiences to not be negative. **You want your kid to feel included and safe.** So much of our society is centered around food.”

- Caregiver










“**I live in constant paranoia.** I’ll get something from the corner store and read the ingredients 5-10 times to be safe. But a little voice tells me not to eat it because something bad will happen.”

- Patient

Nine Food Groups Cause the Majority of Serious Food Allergic Reactions, Extending Far Beyond Peanut

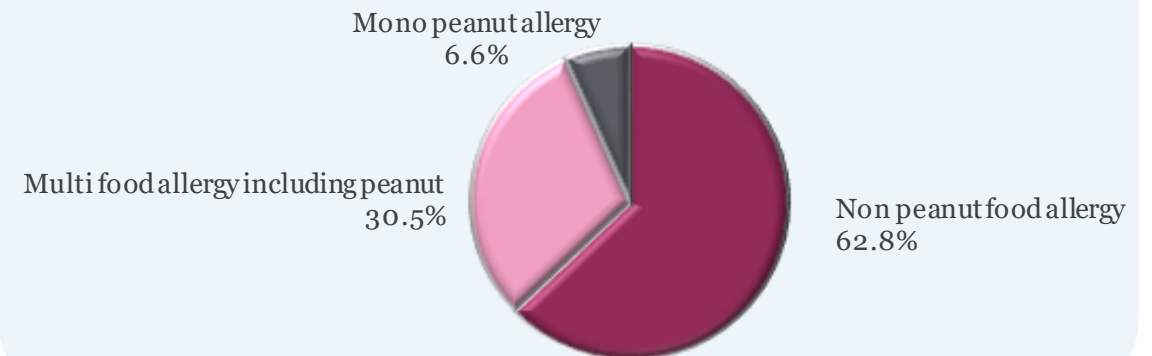
All foods associated with severe reactions; multi-food allergy associated with higher reaction rate

Percent of Group who are Multi-Allergic

 Peanut		 Soy		 Tree Nuts	
Adults	Ped	Adults	Ped	Adults	Ped
68%	55%	81%	75%	90%	90%
 Milk		 Egg		 Sesame	
Adults	Ped	Adults	Ped	Adults	Ped
60%	43%	66%	76%	80%	86%
 Wheat		 Shellfish		 Fin Fish	
Adults	Ped	Adults	Ped	Adults	Ped
68%	67%	76%	74%	90%	84%

U.S. Food Allergy Emergency Department Visits in 12 Month Period

- Less than 7% of ER visits for food allergy are attributed to peanut mono-allergy, including adults & pediatrics.
- There are no approved therapies to treat the vast majority of highly reactive food allergy patients.



A FDA Approved Intervention for Simultaneous Desensitization to Multiple Allergens Would Address Severe Unmet Need

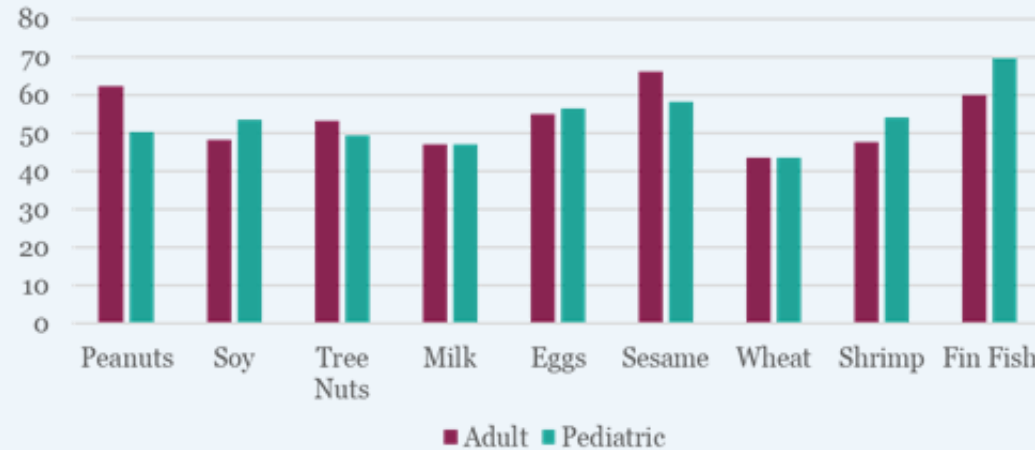
Allergic to multiple foods

Reactions from accidental exposures increase in children who are allergic to more foods

1 food → 0.2 reactions per yr
2 foods → 0.7 reactions per yr
3 foods → 3.4 reactions per yr



Lifetime History of Food Allergy Associated Emergency Department Visits (%)



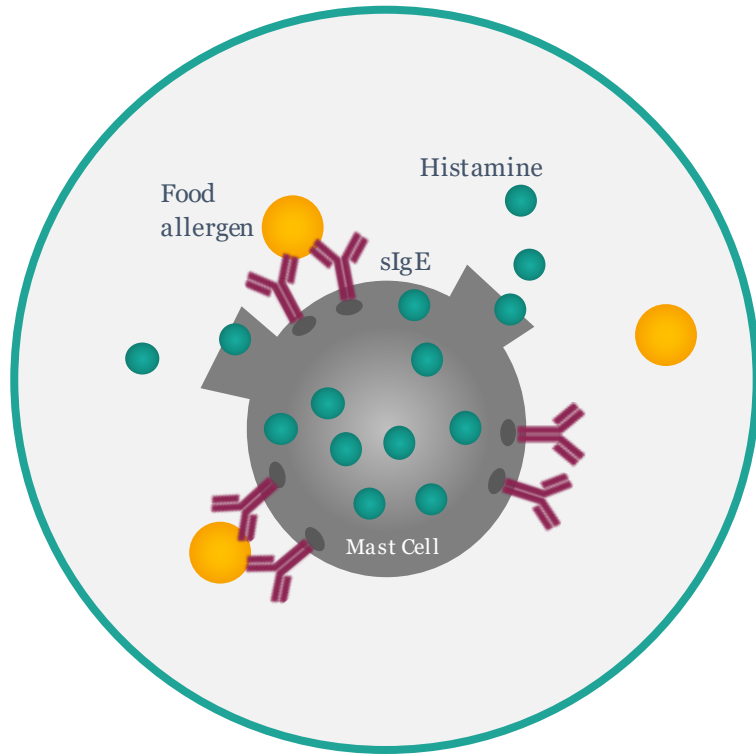
Allergic to foods that are difficult to avoid

“No one is banning milk or eggs from lunch rooms or airplanes”



High anxiety
High psychological burden of disease
Highly motivated to seek therapy

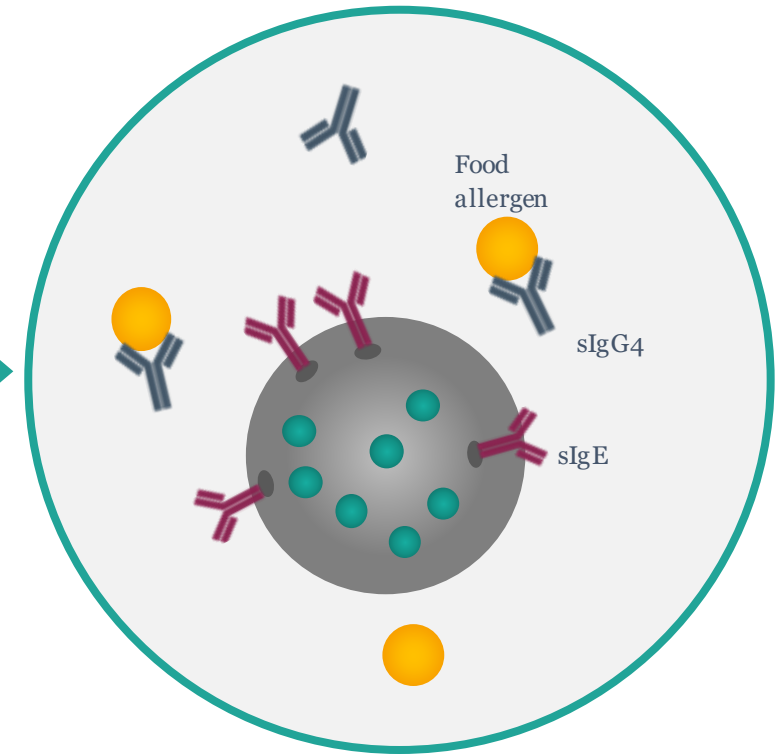
Oral Immunotherapy (OIT): Supervised Allergen Dosing to Retrain the Immune System and Increase Food Tolerance



Pre-OIT

Antigen-specific IgE on the surface of mast cells cross-links with antigen, triggering mast cell degranulation, histamine release, and the inflammatory cascade characteristic of an allergic reaction.

Goal of therapy: Desensitization



Post-OIT

Mechanistic hypothesis: Long term OIT decreases antigen-specific IgE and increases antigen-specific IgG4, which competitively binds antigen. Goal is to decrease risk of mast cell degranulation.

OIT

Gradually increasing allergen exposure followed by long-term maintenance

ADP101 | A Standardized, Pharmaceutical-Grade Multi-Allergen OIT

15 drug substances

Almond	Pecan
Cashew	Pistachio
Cod	Salmon
Egg	Sesame
Hazelnut	Shrimp
Milk	Soy
Peanut	Walnut
Wheat	
+	
Excipient	Flavor Masker

Dry powder drug product to be mixed into vehicle food



Pre-measured unit dosing supports patient-centric dosing protocol



Regulatory Precedent for Licensure

Peanut OIT - Palforzia™ FDA Approval U.S. Label / Data Highlights

Indication

PALFORZIA is an oral immunotherapy indicated for the **mitigation of allergic reactions**, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients **aged 4 through 17 years**. Up-Dosing and Maintenance may be continued in patients 4 years of age and older (2.4). PALFORZIA is to be **used in conjunction with a peanut-avoidant diet**. Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

Contraindicated for Uncontrolled asthma; History of eosinophilic esophagitis or other eosinophilic gastrointestinal disease.

Phase 3 Studies

Phase 3 Safety and Efficacy n=555 Pediatric and Adult

- 20-40 weeks Up-Dosing → 24-28 weeks Maintenance
- Primary efficacy endpoint: % of subjects tolerating a single dose of 600 mg peanut protein in the exit DBPCFC with no more than mild allergic symptoms after 6m of Maintenance treatment.
- Enrollment criteria: Dose limiting symptoms at ≤100 mg peanut protein on Double Blind Placebo Controlled Food Challenge (DBPCFC) (*median eliciting dose 30 mg*)

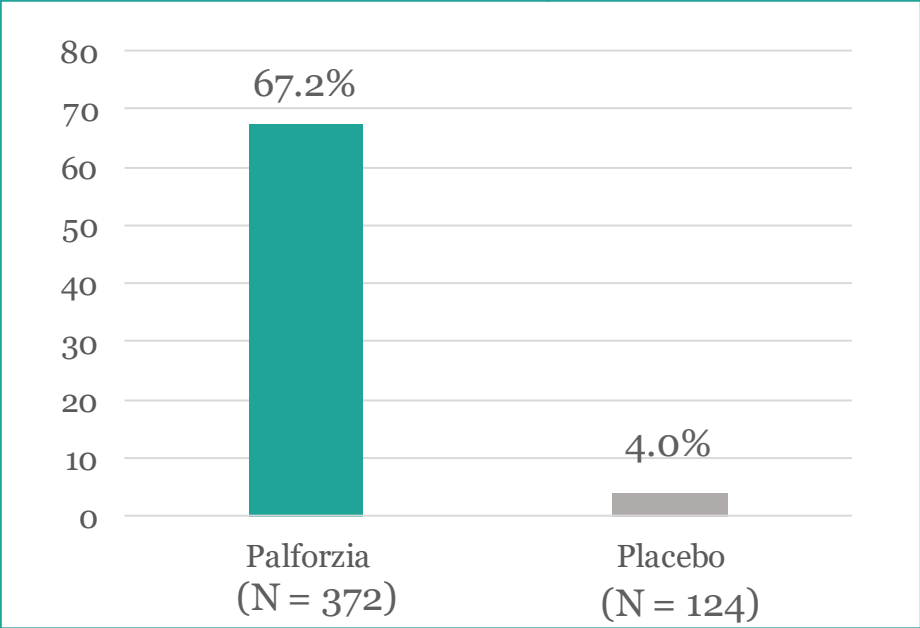
Phase 3 Safety n=506 Pediatric

- 20-40 weeks Up-Dosing → No Maintenance

Study 1: Tolerance 600 mg of peanut on DBPCFC

Response Rate in Intent To Treat population age 4-17

Peanut challenge	600 mg
PALFORZIA (N = 372)	67.2%
Placebo (N = 124)	4.0%
Treatment difference (95% CI)	63.2% (53.0%, 73.3%)
P-value	< 0.0001



[1] Secondary endpoint was considered met if the Farrington-Manning test for a non-zero treatment difference was significant at the two sided 0.05 level.
[2] The primary efficacy endpoint was considered met if the lower bound of the Farrington-Manning 95% CI was greater than the prespecified margin of 15 percentage points
<https://www.fda.gov/media/134838/download>

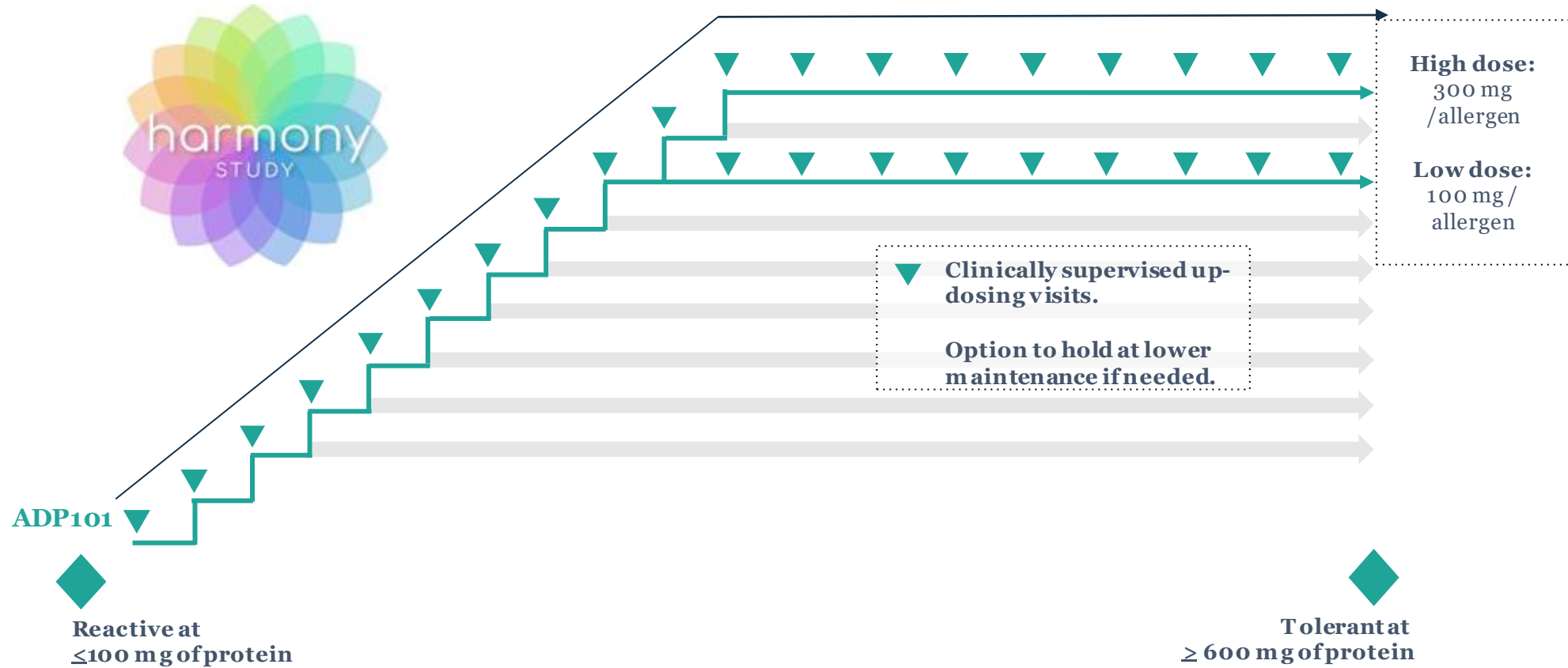
Harmony Phase 1/2 Study Protocol Summary

N=61 peds + 12 adults
with clinical history of
allergy to 1-5 foods.

Multi-center,
randomized, double-
blind, placebo-controlled
study. U.S. only.

Up dosing in clinic +
Daily dosing at home.

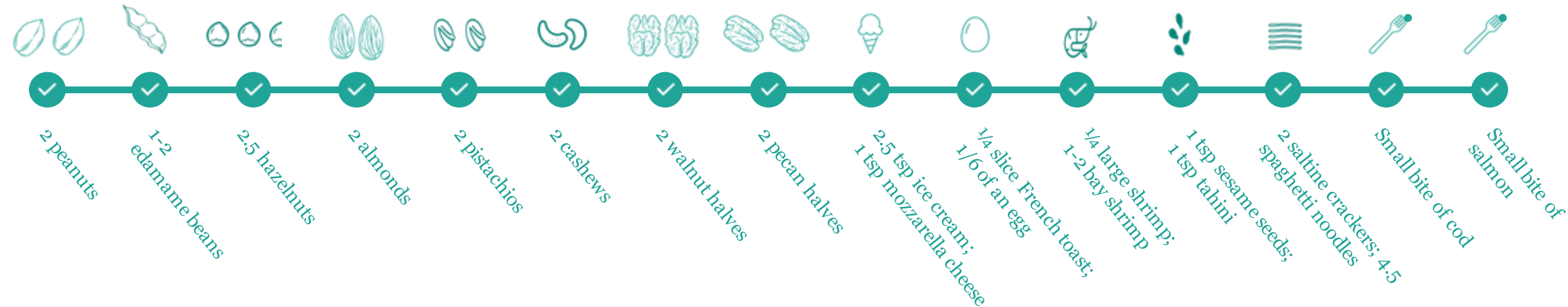
Patients randomized to
high vs low dose
maintenance target.



Primary Objective: Evaluate the efficacy of ADP101 as assessed by the proportion of subjects who tolerate highest dose of at least 600 mg of protein from a relevant food source without dose limiting symptoms at the final/exit double-blind placebo-controlled Food Challenge.

Endpoint Rationale: Raising Reactivity Threshold Above 600 mg of Protein May Provide Meaningful Patient Protection from Accidental Exposures

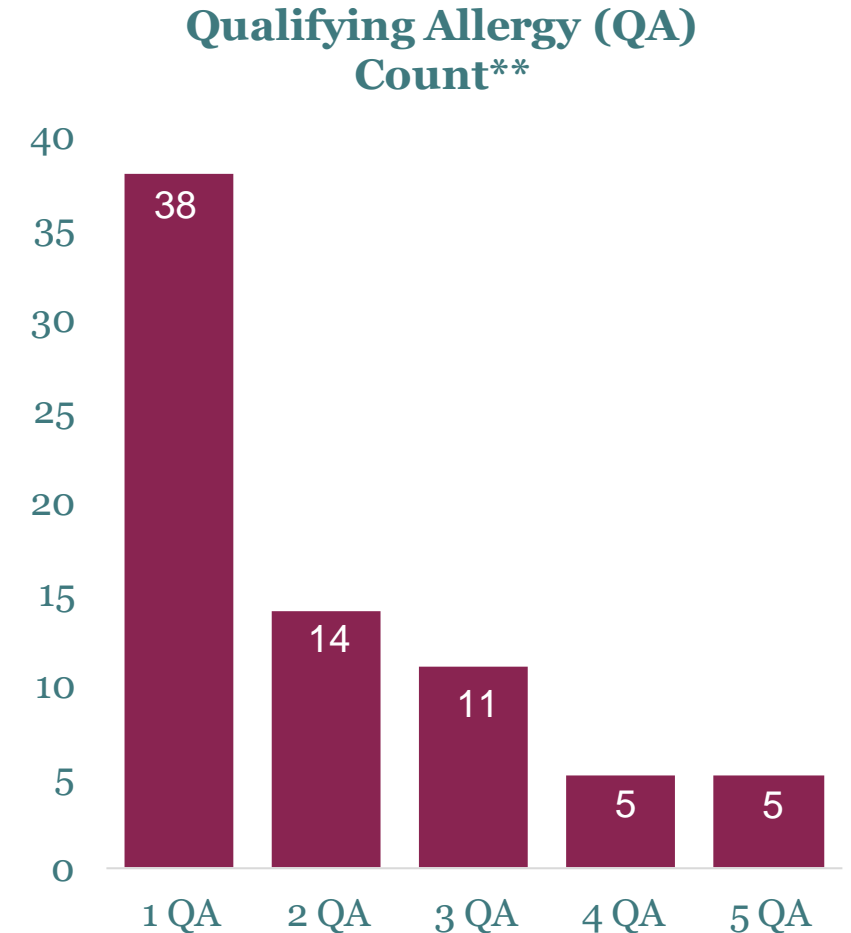
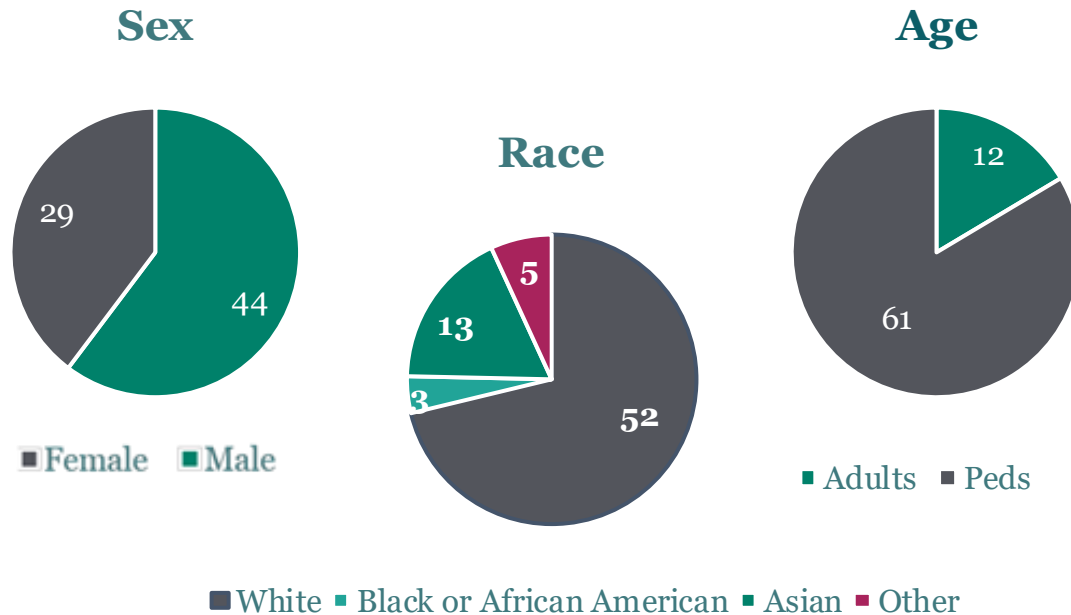
Approximate food equivalents to 600 mg of protein



- The ability to tolerate 600 mg of protein from an accidental exposure would represent a **≥6-fold increase in the amount of allergen tolerated by a patient***.
- Whereas in the past, trace exposures could generate a severe reaction, following therapy, a patient would be expected to tolerate a more substantial accidental exposure (as per equivalents listed above).
- Patients must continue their allergen-avoidance diet and must maintain maintenance dosing.

* for patients starting at 100 mg or below for baseline sensitivity

Harmony Phase 1/2 Study Update – Data expected Q1 2023



4/4 Positive Independent Data Monitoring Committee Reports

- ✓ Continue Trial Without Study Modification – July 2021
- ✓ Continue Trial Without Study Modification – November 2021
- ✓ Continue Trial Without Study Modification – April 2022
- ✓ Continue Trial Without Study Modification – October 2022

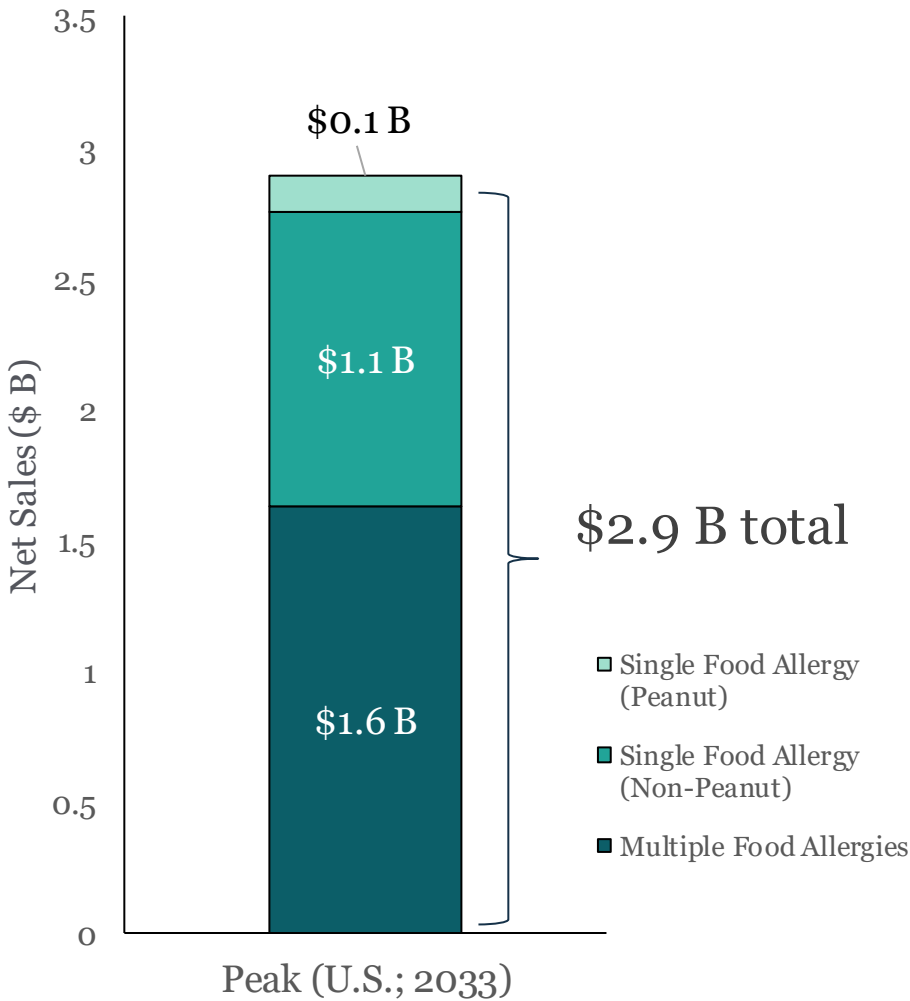
All 15 foods are represented

**QAs = Reactive at ≤ 100 mg protein

Commercial Potential: ADP101 \$2.9B Net Revenue Forecast by 2033

Clearview model assumes target product profile enabled by Harmony study & U.S. pediatric only

Assumption	Peak Value (U.S., 2033)		
Pediatric Diagnosed FA Prevalence	5.6 M		
Target Patient Pop. (Remove infants; Restrict to FA covered by ADP101)	~70%		
Patient Segmentation	Multiple Allergies	Single Allergy (Non-Peanut)	Single Allergy (Peanut)
	40%	45%	15%
Immunotherapy Initiation Rate	6%		
ADP101 Share	90%	55%	25%
Market Access Adjustment (Physician/Payer coverage incomplete)	75%		
Average Duration of Treatment (Up-dosing and maintenance; assumes dropouts)	2.0 Years		
Compliance	80%		
Price at Peak	~\$20 K		
Gross-to-Net (Considers weighted average of rebates)	80%		
Net Revenue (2033)	~\$2.9 B		



Commercial Potential: Food Allergy is the Last Frontier of Atopic Disease

Atopic Disease markets are large, forecasted to grow, and of strategic importance to Pharma

Atopic Dermatitis

U.S. prevalence ~**16.5M**

Allergic Rhinitis

U.S. prevalence ~**24.4M**

Asthma

U.S. prevalence ~**25M**

Food Allergy

U.S. prevalence ~**32M**

Multiple existing and historic blockbusters
across top pharmaceutical companies

Limited interventions:

Epinephrine for rescue

Palforzia® NHSC
pediatric peanut allergy

Atopic diseases with increasingly higher prevalence

Examples of Ongoing Clinical Development Programs Investigating the Role of Biologics to Treat Food Allergy

OuTMATCH Study:

- Omalizumab as monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Participants; Enrollment ongoing. NCT03881696
- Omalizumab (Xolair) marketed by Roche/Genentech and Novartis

Zenith Study:

- Efficacy of Tezepelumab in Peanut Oral Immunotherapy: A Double-Blind, Randomized, Placebo-Controlled Trial (ZENITH – ITN097AD) In startup; to be initiated in Q1 2023; NCT# pending
- Tezepelumab (Tezspire) marketed by Amgen and AstraZeneca

Ligelizumab:

- Efficacy and Safety of QGE031 (Ligelizumab) in Patients With Peanut Allergy; Enrollment ongoing; NCT04984876
- Ligelizumab is an investigational drug owned by Novartis

Phase 3-Scale Build Out Initiated

Advancing Facility and Equipment Workstreams

- Build out initiated for dedicated, 53k ft² facility in Philadelphia metro area
- Designing customized high- throughput equipment
- Will accommodate both manufacturing and final packaging
- Facility is strategically located and integrated with our existing Contract Manufacturing Organization
- Production-ready in 2023



Alladapt Has an Attractive Risk Reward Profile with a Platform That Offers the Opportunity to Catalyze an Entirely New Treatment Category

Food Allergy has a high disease burden

- ✓ Constant, meticulous avoidance of food allergens is standard of care and highly burdensome
- ✓ Alladapt is working to prove that our standardized OIT and dosing protocol meet the threshold for a safe and effective product and offer patients an intervention that is superior to current standards of care

Alladapt is pursuing a near-comprehensive approach:

- ✓ Mono- or multi-allergy across an expansive set of foods
- ✓ Applicable across geographies
- ✓ Pediatrics and adults - US Pediatric opportunity alone is projected to approach \$3 billion

Licensed technology from Stanford University provides scientific underpinning and de-risking

Clinical Milestones

- ✓ Harmony Phase 1/2 enrollment complete Dec 2021 → Last patient out Dec 2022 → Data anticipated Q1 2023
- ✓ Encore Phase 1/2 long term Open Label Extension Study ongoing with annual efficacy readouts
- ✓ Phase 3 initiation 2024 → 18-24 months to recruit → Up-dosing + Maintenance period approx. 12 months

We expect further market segmentation

- ✓ Combo therapy with biologics helps target the hardest to treat OIT population
- ✓ Treatment in multiple settings to reduce therapy burden

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