



**Aimmune Therapeutics is a biopharmaceutical company developing and bringing new treatments to people with potentially life-threatening food allergies.**

### A United Call-to-Action from the Food Allergy Community

At an advocacy-sponsored research retreat in 2011 that was aimed at reaching consensus on the direction of food allergy treatment research, a group of parents of children with severe food allergies, patient advocacy organizations, leading clinical and academic physicians, representatives from the FDA and the National Institutes of Health (NIH), and members of the pharmaceutical industry concluded there was a large need for a structured oral immunotherapy (OIT) approach and treatments. This consensus-driven community ultimately led to the formation of the Allergen Research Corporation, now Aimmune Therapeutics, to specifically address this need and fulfill a unified vision.

### Working to Address a Need in Food Allergy

- Food allergy is a chronic condition in which exposure to a food triggers a harmful immune response, such as anaphylaxis, which can be life-threatening.<sup>1</sup>
- More than 15 million Americans<sup>2,3,4</sup> and more than 17 million Europeans have food allergies.<sup>4</sup> In the U.S. alone, more than 1.6 million children are believed to have a peanut allergy.<sup>2,5</sup>
- Eight major food allergens – milk, egg, peanut, tree nuts, wheat, soy, fish and shellfish – are responsible for most of the serious food allergy reactions in the U.S.<sup>6</sup>
- Allergies to peanut, tree nuts, fish and shellfish are generally lifelong.<sup>6</sup>
- Food allergies are managed through strict avoidance of food allergens and early treatment of allergic reactions following accidental exposure.<sup>7</sup>
- Even trace amounts of a food allergen can cause a reaction.<sup>8-13</sup>
- Each year in the U.S., 200,000 people require emergency medical care for allergic reactions to food.<sup>6</sup>

### CODIT™: Our Structured Approach to Oral Immunotherapy to Treat Food Allergies

- Building on a century of OIT research, our structured CODIT (Characterized Oral Desensitization Immunotherapy) approach is intended to be an optimized approach to food allergy treatment.
- The CODIT protocol involves gradual, controlled up-dosing by a trained allergist in a certified healthcare setting, followed by a daily maintenance dose.



PROGRAM	PRE-IND	PHASE 1/2*	PHASE 3	APPROVED
PALFORZIA (PEANUT)	[Progress bar spanning all stages]			
AR201 (EGG)	[Progress bar spanning PRE-IND and PHASE 1/2]			
AR301 (MULTINUT)	[Progress bar spanning PRE-IND and PHASE 1/2]			

\*Because our treatment product candidates are based on foods that have not shown toxicology issues except in their functions as allergens, we have not been required to and at this time do not anticipate conducting Phase 1 clinical trials.

### First Application of CODIT: PALFORZIA™ [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp], the First Ever FDA-Approved Treatment for Peanut Allergy

- 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. PALFORZIA is to be used in conjunction with a peanut-avoidant diet. PALFORZIA is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- PALFORZIA is a rigorously developed, pharmaceutical-grade oral immunotherapy for peanut allergy with a well-defined allergen profile to assure every dose, whether 0.5 mg (equivalent to 1/600<sup>th</sup> of a peanut) or 300 mg, has been prepared and analyzed for consistency.
- PALFORZIA was approved by the FDA in the United States in January 2020.



Please see additional Safety Information, including Boxed WARNING, on the next page.

### VISION

Become the global leader in developing therapies and solutions for people with food allergies, intolerances and their associated conditions.

### TICKER

AIMT (Nasdaq)

### MANAGEMENT

**Jayson Dallas, MD**  
President & Chief Executive Officer

**Eric Bjerkholt**  
Chief Financial Officer

**Daniel Adelman, MD**  
Chief Medical Officer

**Andrew Oxtoby**  
Chief Commercial Officer

**Samina Bari**  
SVP, Corporate Affairs

**Douglas Sheehy**  
General Counsel & Secretary

**William Turner**  
SVP, Global Regulatory Affairs & Quality Assurance

**Becki Filice**  
SVP, Product & Portfolio Management

**Alicia Goodman**  
SVP, Human Resources

**U.S. HEADQUARTERS**  
Brisbane, CA

**EUROPE HEADQUARTERS**  
London, U.K.

<sup>1</sup> National Institute of Allergy and Infectious Diseases, National Institutes of Health. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. 2010. <http://www.niaid.nih.gov/topics/foodallergy/research/pages/reportfoodallergy.aspx>. <sup>2</sup> United States Census Bureau Quick Facts (2015 estimates). <sup>3</sup> Gupta RS, Springston EE, Warrier MR, et al. The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States. *Pediatrics*. 2011;128(1):e9-17. <sup>4</sup> EAACI Food Allergy & Anaphylaxis Public Declaration. <http://www.eaaci.org/attachments/FoodAllergy&AnaphylaxisPublicDeclaration.pdf>. Updated February 11, 2015. Accessed December 4, 2017. <sup>5</sup> Gupta R, Warren C, Blumenstock J, et al. OR078 The Prevalence of Childhood Food Allergy in the United States: An Update. *Ann Allergy Asthma Immunol*. 2017;119(5 Suppl):S11. <sup>6</sup> FARE. Facts and Statistics. <https://www.foodallergy.org/life-with-food-allergies/food-allergy-101/facts-and-statistics>. Accessed December 4, 2017. <sup>7</sup> U.S. Food and Drug Administration. Food allergies: What you need to know. 2017. <https://www.fda.gov/food/ingredientspackaginglabeling/foodallergens/ucm079311.htm>. <sup>8</sup> Heffo SL, Taylor SL. Allergenicity of edible oils. *Food Technol*. 1999; 53:62-70. <sup>9</sup> Laoprasitth N, Wallen MD, Jones RT, et al. Anaphylaxis in a milk-allergic child following ingestion of lemon sorbet containing trace quantities of milk. *J Food Prot*. 1998;61:1522-1524. <sup>10</sup> Gem JE, Yang E, Ebrard HM, Sampson HA. Allergic reactions to milk-contaminated nondairy products. *N Engl J Med*. 1991; 324:976-979. <sup>11</sup> Yunginger JW, Gauker MB, Jones RT, et al. Use of radioimmunoassay to determine the nature, quantity and source of allergenic contamination of sunflower butter. *J Food Prot*. 1983; 46:625-628. <sup>12</sup> Jones R, Squillace D, Yunginger J. Anaphylaxis in a milk-allergic child after ingestion of milk contaminated kosher-pareve-labeled "dairy-free" dessert. *Ann Allergy*. 1992; 68:223-227. <sup>13</sup> Hourihane J, Kilbrun S, Nordlee J, et al. An evaluation of the sensitivity of subjects with peanut allergy to very low doses of peanut: a randomized, double-blind, placebo-controlled food challenge study. *J Allergy Clin Immunol*. 1997; 100:596-600.

## 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.

PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Limitations of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

## IMPORTANT SAFETY INFORMATION

### WARNING: ANAPHYLAXIS

- **PALFORZIA can cause anaphylaxis, which may be life threatening and can occur at any time during PALFORZIA therapy.**
- **Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.**
- **Do not administer PALFORZIA to patients with uncontrolled asthma.**
- **Dose modifications may be necessary following an anaphylactic reaction.**
- **Observe patients during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes.**
- **PALFORZIA is available only through a restricted program called the PALFORZIA REMS.**

## CONTRAINDICATIONS

Uncontrolled asthma and history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease.

## WARNING AND PRECAUTIONS

### Anaphylaxis

PALFORZIA can cause anaphylaxis, which may be life threatening. PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS because of the risk of anaphylaxis. Only prescribers, healthcare settings, pharmacies, and patients certified and enrolled in the REMS Program can prescribe, receive, dispense or administer PALFORZIA.

Anaphylaxis has been reported during all phases of PALFORZIA dosing, including Maintenance and in subjects who have undergone recommended Up-Dosing and dose modification procedures.

Do not initiate PALFORZIA treatment in a patient who has had severe or life-threatening anaphylaxis within the previous 60 days. PALFORZIA may not be suitable for patients with certain medical conditions that may reduce the ability to survive anaphylaxis, including but not limited to markedly compromised lung function, severe mast cell disorder, or cardiovascular disease. In addition, PALFORZIA may not be suitable for patients taking medications that can inhibit or potentiate the effects of epinephrine.

All Initial Dose Escalation doses and the first dose of each Up-Dosing level must be administered in a certified health care setting.

Patients may be more likely to experience allergic reactions following PALFORZIA administration in the presence of cofactors such as exercise, hot water exposure, intercurrent illness (e.g., viral infection), or fasting. Other potential cofactors may include menstruation, sleep deprivation, nonsteroidal anti-inflammatory drug use, or uncontrolled asthma. Patients should be proactively counseled about the potential for the increased risk of anaphylaxis in the presence of these cofactors. If possible, adjust the time of dosing to avoid these cofactors. If it is not possible to avoid these cofactors, consider withholding PALFORZIA temporarily.

### Asthma

Uncontrolled asthma is a risk factor for a serious outcome, including death, in anaphylaxis. Ensure patients with asthma have their asthma under control prior to initiation of PALFORZIA.

PALFORZIA should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Following resolution of the exacerbation, resumption of PALFORZIA should be undertaken cautiously. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of PALFORZIA.

### Eosinophilic Gastrointestinal Disease

Discontinue PALFORZIA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastrointestinal symptoms, including dysphagia, vomiting, nausea, gastroesophageal reflux, chest pain, or abdominal pain.

### Gastrointestinal Adverse Reactions

Gastrointestinal adverse reactions were commonly reported in PALFORZIA-treated subjects, and dose modification should be considered for patients who report these reactions. For severe or persistent gastrointestinal symptoms consider a diagnosis of eosinophilic esophagitis.

## ADVERSE REACTIONS

The most common adverse events reported in subjects treated with PALFORZIA (incidence  $\geq 5\%$  and  $\geq 5\%$  than placebo) are abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

**Please see full Prescribing Information, including Boxed WARNING, and Medication Guide at [www.PALFORZIA.com](http://www.PALFORZIA.com).**

**For more information about PALFORZIA, please call 1-844-PALFORZ (1-844-725-3679) or visit [www.PALFORZIA.com](http://www.PALFORZIA.com).**