# Aimmune to Present New Data on Safety and Efficacy of AR101, Clinical Practice Implementation of Oral Immunotherapy, Quality of Life and Other Related Studies at ACAAI 2019

BRISBANE, Calif.--(BUSINESS WIRE)--Oct. 31, 2019-- Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced it will present new data on the safety and efficacy of the company's lead investigational candidate, AR101 (trade name Palforzia™), at the American College of Asthma, Allergy and Immunology (ACAAI) Annual Scientific Meeting, taking place November 7-11, 2019, in Houston. Additional highlights include data from a half dozen studies, including real-world insights regarding the implementation of oral immunotherapy into clinical practice. AR101 is Aimmune's investigational biologic oral immunotherapy for desensitization of patients with peanut allergy that currently is under review by the U.S Food and Drug Administration (FDA).

"We're pleased to be presenting a robust and diverse set of studies related to peanut allergy, ranging from its diagnosis, associated costs and effects on quality of life, to patient selection and integration of potential treatments in clinical practice," said Daniel Adelman, M.D., Chief Medical Officer of Aimmune. "The progress we and others have made on behalf of patients and families affected by living with peanut allergies in just the past 12 months has been inspiring and we look forward to learning about additional important advances at this year's ACAAI meeting."

Presentation Details:

**#P303:** Sher *et al.*, Safety and Efficacy Comparison: ARTEMIS and PALISADE Phase 3 Studies of AR101 in Peanut Allergy
3:45-4:00 pm CST, Friday, November 8
LOCATION: George R. Brown Convention Center, Halls A3 & B3 (Level 3) Monitor 7

**#P304:** Tilles *et al.*, Prevalence of Peanut Allergy and Incidence of Related Healthcare Resource Utilization: A US Claims Analysis
4:00-4:15 pm CST, Friday, November 8
LOCATION: George R. Brown Convention Center, Halls A3 & B3 (Level 3) Monitor 7

**#P305:** Hartman *et al.*, Reported Practice Logistics for Implementation of Subcutaneous Immunotherapy Versus Food Oral Immunotherapy Among US-Based Allergists/Immunologists
4:15-4:30 pm CST, Friday, November 8
LOCATION: George R. Brown Convention Center, Halls A3 & B3 (Level 3) Monitor 7

**#P306:** Vickery *et al.*, Identifying AR101-Eligible Patients Without an Oral Food Challenge: PALISADE Peanut-Specific IgE Versus Food Challenge Data
4:30-4:45 pm CST, Friday, November 8
LOCATION: George R. Brown Convention Center, Halls A3 & B3 (Level 3) Monitor 7

**#P308:** Bird *et al.*, Response to AR101 by Baseline Peanut-Specific IgE and Skin Prick Test: Results from PALISADE
5:00-5:15 pm CST, Friday, November 8
LOCATION: George R. Brown Convention Center, Halls A3 & B3 (Level 3) Monitor 7

**#P313:** Nowak-Wegrzyn *et al.*, Peanut Allergy Burden Survey: Health-Related Quality of Life Among Adults in the United States
11:45 am-12:00 pm CST, Saturday, November 9
LOCATION: George R. Brown Convention Center, Halls A3 & B3 (Level 3) Monitor 7

**#P314:** McCann *et al.*, Peanut Allergy Burden Survey: Health-Related Concerns Among Caregivers in the United States
12:00-12:15 pm CST, Saturday, November 9
LOCATION: George R. Brown Convention Center, Halls A3 & B3 (Level 3) Monitor 7

**About AR101**

AR101 is an investigational, peanut-derived, biologic drug candidate for use in oral immunotherapy in patients with peanut allergy. The drug candidate, which is manufactured in accordance with current Good Manufacturing Practices (cGMP), delivers a daily dose of peanut protein with a consistent protein profile, analyzed to ensure reliable major allergen content. The amount of active ingredient in each AR101 capsule is controlled to ensure

minimal variability of allergen content across doses of a given strength. AR101 is administered as an oral powder in graduated doses in pull-apart capsules or foil-laminate sachets. The contents are mixed thoroughly with a few spoonfuls of age-appropriate, unheated food of the patient's choice.

**About Aimmune**

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing oral treatments for potentially life-threatening food allergies. The Company's **C**haracterized **O**ral **D**esensitization **I**mmuno**T**herapy (CODIT™) approach is intended to provide meaningful levels of protection against allergic reactions resulting from exposure to food allergens by desensitizing patients with defined, precise amounts of key allergens. Aimmune's first, investigational, complex biologic product candidate, AR101, is being developed as a treatment to reduce the frequency and severity of adverse events following exposure to peanut. The BLA for AR101 is under review by the FDA, which granted AR101 Breakthrough Therapy Designation in 2015 for the desensitization of peanut-allergic patients 4 to 17 years of age. The European Medicines Agency (EMA) is reviewing Aimmune's Marketing Authorization Application (MAA) for AR101 which Aimmune submitted in June 2019. Aimmune initiated a randomized phase 2 clinical trial of its second investigational, complex biologic product, AR201, for the treatment of egg allergy in August 2019. For more information, please see www.aimmune.com.

**Forward-Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: Aimmune's expectations regarding the potential benefits of AR101 and AR201; and Aimmune's expectations regarding potential applications of the CODIT™ approach to treating potentially life-threatening food allergies. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the expectation that Aimmune will need additional funds to finance its operations; the unpredictability of the regulatory process; the possibility that Aimmune's or any of its collaborative partners' clinical trials will not be successful; Aimmune's dependence on the success of AR101; Aimmune's reliance on third parties for the manufacture of Aimmune's product candidates; possible regulatory developments in the United States and foreign countries; and Aimmune's ability to attract and retain senior management personnel. These and other risks and uncertainties are described more fully in Aimmune's most recent filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2019. All forward-looking statements contained in this press release speak only as of the date on which they were made. Aimmune undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

This press release concerns AR101 and AR201, product candidates that are under clinical investigation. Neither AR101 nor AR201 has been approved for marketing by the FDA or the EMA. AR101 and AR201 are currently limited to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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