Data from Two Studies Confirm Quality of Life and Psychosocial Burden of Living with Peanut Allergy

--APPEAL 2: Struggle to Avoid Accidental Peanut Exposure Negatively Impacts Quality of Life for Patients and Families--

--Phase 3 PALISADE Follow-on Study Analysis: Improvements in Quality of Life for Peanut-Allergic Patients after Continued AR101 Treatment--

LISBON, Portugal--(BUSINESS WIRE)--Jun. 4, 2019-- Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced new data from two studies that assessed the psychosocial burden of living with peanut allergy. Results from APPEAL 2, the first European multi-country qualitative evaluation of the impact of living with peanut allergy, found that living in fear of a potentially fatal reaction to peanuts significantly impacts the quality of life of individuals with peanut allergy and their families. In addition, data from an analysis of patients who received daily treatment with AR101 during the open-label extension of the Phase 3 PALISADE trial, ARC004, showed they experienced clinically meaningful improvements in disease-specific quality of life. AR101 is an investigational biologic drug for use in oral immunotherapy as a treatment to reduce the frequency and severity of allergic reactions following exposure to peanuts. These data were presented here in a late-breaking poster discussion session and in an oral session, respectively, at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2019 in Lisbon.

“Across Europe, individuals and families are failing to cope with peanut allergy through a strategy of avoidance of peanuts,” said Audrey DunnGalvin, Ph.D., investigator of both APPEAL 1 and APPEAL 2 and a lecturer in the School of Applied Psychology at University College Cork in Cork, Ireland. “Both our qualitative and quantitative research shows how fear, frustration and uncertainty are the hallmarks of living with peanut allergy, negatively affecting the day-to-day lives of both patients and their families.”

APPEAL 2 was conducted to gather qualitative data to build upon the findings of APPEAL 1, the first European multi-country quantitative study to assess the psychosocial burden and impact on daily activities in peanut-allergic individuals and their families.

The results of APPEAL 2 amplify the findings of APPEAL 1, showing that peanut allergy affects the lives of peanut-allergic individuals both emotionally and socially, as well as their relationships and daily coping behaviors as they attempt to avoid peanuts and prepare for a reaction in the event of an accidental exposure. Furthermore, peanut-allergic individuals are more likely to experience feeling different, isolated, and restricted of social activities as compared with caregivers, who more often experience stress and adverse impacts on work and career. Both those with peanut allergy and caregivers experience anxiety, worry, sadness, and annoyance, and reported their lives are adversely affected by peanut avoidance, reactions to peanuts, and the fear of reacting to peanuts.

Separately, data from the six-month open-label extension study of PALISADE showed that children receiving the therapeutic dose of AR101 (300 mg/day) for an additional 28 weeks reported improvements in all domains of the Food Allergy Quality of Life Questionnaire (FAQLQ), as well as in the self-reported food allergy specific independent measure (FAIM). The mean (95% CI) change in self-reported FAQLQ domains was greater than the estimated minimal important difference (MID), or the smallest benefit that a patient would say is valuable. Furthermore, improvements over time in domains of FAQLQ and FAIM may reflect the need for the patients and caregivers to adjust to their desensitization status. These improvements in quality of life are consistent with recent findings from a two-year longitudinal study of changes in quality of life due to peanut oral immunotherapy and represent the first data from a clinical trial showing positive changes in food allergy-related quality of life.

“We are encouraged that daily dosing with AR101 in the open-label extension trial resulted in important and clinically meaningful improvements in disease-specific quality-of-life measures in children with peanut allergy,” said Prof. Jonathan Hourihane, MB, BCh., BAO, investigator with the PALISADE trial and Professor of Paediatrics and Child Health at University College Cork in Ireland. “Given that quality of life improves in treated patients once they know they have been desensitized, treatment with AR101 may help relieve the anxiety, fear, and social limitations that are a current reality for individuals and families who live with peanut allergy.”

About the APPEAL Studies

APPEAL 1 (**A**llergy to **P**eanuts Im**P**acting **E**motions **A**nd **L**ife 1) collected data from 1,846 participants in eight European countries and was the first pan-European quantitative, cross-sectional survey that explored the psychosocial impacts of living with PA with use of a novel questionnaire. APPEAL 2 (**A**llergy to **P**eanuts Im**P**acting **E**motions **A**nd **L**ife 2), was the first qualitative evaluation of the impact of living with peanut allergy

conducted across multiple European countries. Researchers interviewed 146 individuals with moderate-to-severe peanut allergies– 39 adults ages 18 to 30 years, 39 adolescents ages 13 to 17 years, and 24 children ages 8 to 12 years, as well as 44 caregivers of peanut-allergic individuals ages 4 to 17 years. The goal of the study was to identify concepts important to peanut-allergic individuals and their parents/caregivers, as well as to compare and contrast the impact of peanut allergy between countries and groups.

About the PALISADE Open-Label Extension Trial

A total of 110 children ages 4 to 17 with peanut allergy participated in a six-month open-label extension trial of daily AR101 maintenance therapy after they had completed the double-blind, placebo-controlled, Phase 3 PALISADE trial. Of these, 68 children and 93 parents/caregivers completed an age-appropriate Food Allergy Quality of Life Questionnaire (FAQLQ) at screening and after the open-label extension. At screening, 67.3% of participants had experienced one or more anaphylactic reactions to peanut allergy in their lifetime.

About PALISADE

The international, randomized, double-blind, placebo-controlled Phase 3 PALISADE (**P**eanut **Al**lergy oral **I**mmunotherapy **S**tudy of **A**R101 for **De**sensitization) trial evaluated the efficacy and safety of AR101 in patients with peanut allergy. PALISADE was conducted at 66 sites in 10 countries in North America and Europe. A total of 496 patients ages 4 to 17 were randomized 3:1 to receive AR101 or placebo along with 55 adults ages 18 to 49 who were not part of the primary analysis. To meet PALISADE's inclusion criteria, patients could tolerate no more than the 30-mg dose of peanut protein in an entry double-blind, placebo-controlled food challenge (DBPCFC), which consisted of consecutive doses of 1, 3, 10, 30 and 100 mg of peanut protein, given 20 to 30 minutes apart, and associated with only mild symptoms.

Patients enrolled in PALISADE underwent a dose escalation period of approximately 22 weeks to reach a therapeutic dose of 300 mg per day of AR101 or placebo, then continued with the daily therapeutic dose at 300 mg per day of AR101 or placebo for approximately six months. At that point, patients underwent an exit DBPCFC, which tested consecutive doses of 3, 10, 30, 100, 300, 600 and 1,000 mg of peanut protein, given 20 to 30 minutes apart, and associated with only mild symptoms. Both the entry and exit DBPCFCs used an independent, blinded assessor. Following the completion of the exit DBPCFC, patients were unblinded and eligible to rollover or crossover into the follow-on ARC004 clinical trial, as appropriate.

Full results from the PALISADE trial were published in the *New England Journal of Medicine* in November 2018.1

About Peanut Allergy

Peanut allergy is one of the most common food allergies, affecting more than 6 million people in the U.S. and Europe, and reactions to peanut are often severe and potentially life-threatening. Peanut allergy usually persists into adulthood2,3,4, 5 and while rare, accounts for the majority of deaths related to food allergy.6 There are no approved treatment options for peanut allergy.7 The standard of care has been a strict elimination diet and the timely administration of rescue medications in case of an allergic reaction from accidental exposure.8,9,10 Despite vigilance, accidental exposures may occur11 and cause reactions of unpredictable severity,12 leading to a lifelong risk of severe reactions.

About AR101

AR101 is a new, peanut-derived investigational oral biologic drug for use in oral immunotherapy in patients with peanut allergy. The drug, 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.

Aimmune's Biologics License Application (BLA) for AR101 was accepted for review by the U.S. Food and Drug Administration (FDA) in March 2019. The Allergenic Products Advisory Committee (APAC) of the FDA will review the BLA for AR101 at its meeting scheduled for September 13, 2019. The company plans to submit a Marketing Authorization Application (MAA) for AR101 to the European Medicines Agency in mid-2019.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing oral treatments for 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 biologic product, 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 U.S. FDA, which in 2015 granted AR101 Breakthrough Therapy Designation for the desensitization of peanut-allergic patients 4 to 17 years of age. Aimmune expects to file for marketing approval of AR101 in Europe in mid-2019. Aimmune has filed an IND application for its second product, AR201 for the treatment of egg allergy, and intends to start a randomized Phase 2 clinical trial in mid-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, including relief from emotional and other factors that negatively impact quality of life; Aimmune’s expectations regarding the review of the BLA for AR101 by the FDA and APAC; Aimmune’s expectations regarding the planned timing and filing for marketing approval of AR101 in Europe; Aimmune’s expectations on the timing of initiating a phase 2 clinical trial for AR201;and Aimmune’s expectations regarding potential applications of the CODIT™ approach to treating life-threatening food allergies. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: Aimmune’s or any of its collaborative partners’ ability to initiate and/or complete clinical trials; 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 March 31, 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, a product candidate that is under clinical investigation, and AR201, a product candidate that Aimmune expects will be under clinical investigation in 2019. Neither AR101 nor AR201 has been approved for marketing by the FDA or the European Medicines Agency (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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