Aimmune Therapeutics to Present AR101, OIT and Peanut Allergy Data at 2019 AAAAI Annual Meeting

— Nine Abstracts Featured, Including Data on Longer-Term AR101 Efficacy and Safety and PALISADE Accidental Exposures —

BRISBANE, Calif.--(BUSINESS WIRE)--Feb. 4, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced that it will present data on AR101, oral immunotherapy, and peanut allergy at the 2019 American Academy of Asthma, Allergy and Immunology (AAAAI) Annual Meeting, taking place February 22–25 in San Francisco. All abstracts for the 2019 AAAAI Annual Meeting, which focuses on “Food Allergy: Advances in Prevention and Treatment,” are available at https://www.jacionline.org/issue/S0091-6749(18)X0004-9.

“We are excited by the new data being presented at AAAAI, which deepen our understanding of AR101 and how it may benefit children, teens and families struggling with the uncertainty of life with peanut allergy,” said Daniel Adelman, M.D., Chief Medical Officer of Aimmune. “Our goal with AR101 oral immunotherapy is to train the immune system so that allergic reactions with accidental exposures are less frequent and severe. Taken together, the new data presented at AAAAI help to elucidate how AR101 delivers on our therapeutic thesis, providing continued immunomodulation throughout the course of the treatment period studied, as evidenced by greatly reduced adverse events due to accidental exposures to peanuts. These data provide further evidence of the effects demonstrated in the exit food challenge in PALISADE, with a 94% reduction of epinephrine use in the AR101-treated patients at the 600-mg exit food challenge dose. Also, we are seeing increases in efficacy over time, as nearly two thirds of the AR101 patients who tolerated less than the highest dose at the PALISADE exit were able to tolerate more peanut protein in the follow-on study challenge, and half the patients overall were able to tolerate 2,000 mg as the single highest tolerated dose.”

Presentation details are as follows:

AR101 Clinical Trial Data

#P468: *Wang et al.*, Impact of Peanut Allergy on Quality of Life: Baseline Results from PALISADE, a Phase 3, Double-Blind, Placebo-Controlled Trial for AR101 Oral Immunotherapy
Sunday, February 24, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

#P742: *Goldsobel et al.*, Identification of Peanut-Allergic Participants for Oral Immunotherapy with AR101 Using Clinical Reaction History and Immunologic Markers Without Oral Food Challenge – A Comparison Between RAMSES and PALISADE Trials
Monday, February 25, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

#P776: *Carr et al.*, Longer-Term Safety and Efficacy Measures of AR101 Oral Immunotherapy for Peanut Allergy: Results from a Phase 3 Follow-On Study
Monday, February 25, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

#P796: *Carr et al.*, Estimating the Probability of Tolerating Each Challenge Dose of Peanut Protein at Exit Double-Blind, Placebo-Controlled Food Challenge: Results from a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial (PALISADE) of AR101
Monday, February 25, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

#P804: *Hourihane et al.*, Accidental Exposures to Peanut and Other Food Allergens: Results from a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial (PALISADE)
Monday, February 25, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

#P819: *Johnston et al.*, Prevalence of Comorbidities with Peanut Allergy: Results from a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial (PALISADE)
Monday, February 25, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

Additional Peanut Allergy and OIT Data

#P163: *DunnGalvin et al.*, APPEAL (Allergy to Peanuts ImPacting Emotions and Life): Pan-European Results on

Peanut Allergy Impact on Allergic Individuals, Parents and Caregivers
Saturday, February 23, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

#P478:*Mahr et al.*, High Comorbidity Burden and Rates of Severe Reactions in Young Patients with Peanut Allergy
Sunday, February 24, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

#P810:*Ciaccio et al.*, Preferences in Terminology Used to Describe Oral Immunotherapy Varies Based on Physician Utilization
Monday, February 25, 9:45 a.m. – 10:45 a.m. PST
Moscone Center South, Exhibition Level, Hall B

In addition, Aimmune will host a Corporate Symposium, "The Future of Food Allergy: Demystifying OIT," on Friday, February 22, from 6:30 – 8:30 p.m. PST at the Marriott Marquis, Yerba Buena Salon 9.

AR101 is a complex biologic drug under investigation for the treatment of children and adolescents with peanut allergy. The U.S. Food and Drug Administration (FDA) granted AR101 Fast Track Designation for peanut allergy in September 2014 and Breakthrough Therapy Designation for peanut allergy in ages 4–17 in June 2015.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing treatments for life-threatening food allergies. The company's Characterized Oral Desensitization ImmunoTherapy (CODIT™) approach is intended to provide meaningful levels of protection against allergic reactions resulting from accidental exposure to food allergens by desensitizing patients with defined, precise amounts of key allergens. Aimmune's first investigational biologic product using CODIT™, AR101 for the treatment of peanut allergy, has received the FDA's Breakthrough Therapy Designation for the desensitization of peanut-allergic patients 4–17 years of age. Aimmune's regulatory filing for marketing approval of AR101 in the United States (submitted 4Q18) and Europe (anticipated in 1H19) are based on data from the pivotal Phase 3 PALISADE clinical trial of AR101, which in 4–17-year-old subjects met its primary and key secondary endpoints, and additional ongoing and completed AR101 clinical trials. 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 the first half of 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 presentation of data on AR101, oral immunotherapy and peanut allergy at the 2019 American Academy of Asthma, Allergy and Immunology (AAAAI) Annual Meeting; Aimmune's expectations regarding the potential benefits of AR101; Aimmune's expectations regarding AR101's ability to provide continued immunomodulation throughout the course of the treatment period; Aimmune's expectations on regulatory submissions for marketing approval of AR101 for peanut allergy 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: the expectation that Aimmune will need additional funds to finance its operations; 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 September 30, 2018. 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 that is under clinical investigation, and AR201, a product that Aimmune expects will be under clinical investigation in 2019. Neither AR101 nor AR201 has been approved for marketing by the U.S. Food and Drug Administration (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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