New Data Presented at ACAAI 2019 Show Importance of Clinical History in Identifying AR101-Eligibile Patients for PALISADE Study without a Food Challenge

— Findings Suggest that a Strong Clinical History, in Combination with Evidence of Peanut Sensitization, is the Optimal Approach to Identify Highly Sensitive Peanut-Allergic Patients —

HOUSTON--(BUSINESS WIRE)--Nov. 8, 2019-- Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today presented new data showing that a strong clinical history, in combination with evidence of peanut sensitization, is the optimal approach to identify peanut-allergic patients who are highly sensitive to peanut protein. These data were presented at the American College of Asthma, Allergy and Immunology (ACAAI) Annual Scientific Meeting in Houston.

Symptoms of peanut allergy can vary from person to person, which is why diagnosis can be complicated as a single individual may not always experience the same symptoms during every reaction. According to the ACAAI, a skin test or blood test is recommended to help diagnose a peanut allergy or allergy to another substance. An allergist may also recommend an oral food challenge, during which a patient will be fed tiny amounts of peanut or peanut-based products in increasing doses over time in an allergist’s office or a food challenge center.1

“These results demonstrate that many highly allergic patients would have been inappropriately excluded from the pivotal phase 3 PALISADE study of AR101 had eligibility been based on the commonly used 15 kUA/L psIgE threshold combined with clinical history,” said Brian Vickery, MD, principal study investigator and Associate Professor of Pediatrics at Emory University and Director of the Food Allergy Center at Children’s Healthcare of Atlanta. “As the diagnosis process from individual to individual can vary, the findings from the data at ACAAI suggest that the best way to identify peanut allergic patients who are highly sensitive to peanut protein is a strong clinical history in combination with evidence of peanut sensitization.”

Peanut-specific immunoglobin E (psIgE) is often used as a tool to diagnose peanut allergy. The study of 663 patients with clinical history of peanut allergy between the ages of 4-17 was conducted to determine whether using a psIgE threshold of 15 kUA/L alone would identify PALISADE-eligible subjects, who reacted to ≤100 mg peanut protein as a single dose (144 mg cumulative) during a Double-Blind Placebo Controlled Food Challenge (DBPCFC).

Among the 663 patients with an evaluable psIgE value, 537 reacted to ≤100 mg peanut protein (highest tolerated dose ≤30 mg peanut protein) at screening DBPCFC. At the 95% Positive Predictive Value (psIgE=15 kUA/L) according to the Sampson criteria2,115 patients (17.3%) would have been inappropriately excluded from PALISADE had only psIgE been used as a selection tool.

PALISADE was a phase 3, randomized, double-blind, placebo-controlled trial of AR101 for peanut oral immunotherapy. A large cohort of peanut allergic individuals were screened for enrollment using DBPCFC and serum psIgE levels, among other measures, for trial inclusion. All individuals enrolled in the trial had a compelling history of peanut allergy prior to skin prick test or psIgE determination.

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 Biologics License Application (BLA) for AR101 is under review by the U.S. Food and Drug Administration (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: the process related to an oral food challenge, Aimmune’s expectations regarding the potential benefits of AR101; 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 September 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.

References
[1] Peanut Allergy Overview. (2019, March 14). Retrieved from ACAAI: https://acaai.org/allergies/types/food-allergies/types-food-allergy/peanut-allergy
[2] Sampson HA, Ho DG, Relationship between food-specific IgE concentrations and the risk of positive food challenges in children and adolescents. J Allergy Clin Immunol. 1997;100(4):444-451.

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