Aimmune Therapeutics Presents New AR101 Data at AAAAI, Including Demonstrated Reduction in Accidental Exposures to Peanut Requiring Treatment

— AR101 Associated with 70% Reduction in Allergic Reactions Due to Accidental Exposures That Required Treatment Compared to Placebo After Dose Escalation in PALISADE —
— AR101-Treated Patients Who Completed PALISADE Had 95% Increased Probability of Tolerating Any Dose of Peanut Protein in Exit Challenge Compared to Placebo —
— Tolerated Dose Increased for Two Thirds of AR101-Treated Patients in Challenge in PALISADE Follow-on Trial —

BRISBANE, Calif.--(BUSINESS WIRE)--Feb. 25, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today presented new data on AR101, its investigational treatment for peanut allergy, at the American Academy of Asthma, Allergy and Immunology (AAAAI) Annual Meeting in San Francisco, where the company presented nine abstracts overall.

Key presentations demonstrated that AR101 treatment reduced accidental exposures to peanut requiring medication and, for participants who completed the exit food challenge at approximately 12 months, increased the probability of tolerating any dose of peanut protein by 95%. In addition, data from the open-label follow-on trial to PALISADE, ARC004, showed that two thirds of the patients treated for an additional six months with daily AR101 tolerated increased amounts of peanut protein.

“The difficulty of relying on avoidance to manage food allergies was underscored in PALISADE where, even in the focused environment of a clinical trial with daily reminders to avoid peanuts, accidental exposures still occurred,” said Jonathan Hourihane, M.D., Professor of Paediatrics and Child Health at University College Cork and a member of the Aimmune Scientific Advisory Board. “It’s quite interesting to see that the AR101-treated patients not only had fewer reactions to peanut requiring treatment, but also to other food allergens, despite both the active and placebo groups having similar numbers of multi-allergic patients. We look forward to additional data to confirm these observations from ongoing studies.”

“Getting longer-term AR101 data is really exciting, as it shows us the pattern of patients progressing from a roughly 12-month period of elevated peanut-specific IgE to a period of continued immunomodulation, as evidenced by further reductions in specific IgE levels,” said Daniel Adelman, M.D., Chief Medical Officer of Aimmune. “We call those first approximately 12 months (the period of initial desensitization), when patients are most likely to experience symptoms, the high IgE, or “HIgE” phase. After that period, when peanut-specific IgE returns to baseline and, for most patients, continues to drop, patients should expect fewer symptoms. This was seen in the PALISADE follow-on trial, ARC004, along with increases in the amount of peanut protein tolerated.”

Summary of Key Abstracts

Abstract #804:

- Data from PALISADE, a pivotal phase 3 trial that included 496 patients ages 4–17 (372 AR101-treated patients and 124 placebo patients), showed that fewer AR101-treated patients reported accidental exposures to peanuts requiring treatment (6.5%) compared to placebo patients (10.5%).
- During the second six months of PALISADE, there was a 70% reduction in the percentage of AR101-treated patients who required treatment for peanut-related accidental exposures compared to placebo patients (1.6% vs. 5.1%).
- No AR101-treated patients required epinephrine for accidental peanut exposure, compared to 2.4% of placebo patients.
- In addition, AR101-treated patients reported fewer accidental exposures to non-peanut food allergens compared to placebo patients over the full length of PALISADE (13.4% vs. 22.6%) and an even greater reduction during the second six months of treatment (7.4% vs. 15.3%).

Abstract #796:

- Consistent with results previously reported for the 12-month exit food challenge in PALISADE, an additional analysis showed that AR101-treated patients who completed the exit food challenge had a 95% increased probability of tolerating any peanut protein challenge dose compared to placebo patients.

Abstract #776:

- Longer-term data from study ARC004, an open-label follow-on trial to PALISADE, showed that nearly two thirds of the AR101-treated patients taking a daily 300-mg therapeutic dose who tolerated less than the

highest dose at the PALISADE exit challenge (1,000 mg single dose) were able to tolerate more peanut protein at another challenge 28 weeks later. In addition, half the AR101-treated patients taking a daily therapeutic dose were able to tolerate the highest single dose tested (2,000 mg), which was twice the highest dose level administered in PALISADE.

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 mid-2019) 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 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; 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: 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.

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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https://swkhold.investorroom.com/2019-02-25-Aimmune-Therapeutics-Presents-New-AR101-Data-at-AAAAI-Including-Demonstrated-Reduction-in-Accidental-Exposures-to-Peanut-Requiring-Treatment