AR101 Demonstrates Consistent Efficacy and Safety in New Analysis at ACAAI Comparing PALISADE and ARTEMIS Phase 3 Clinical Data

—Despite Differing Study Designs, Patient Criteria and Geographies of the Two Landmark Clinical Trials, Results Were Consistent for AR101-Treated Patients Compared to Placebo—

HOUSTON--(BUSINESS WIRE)--Nov. 8, 2019-- Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced the results from a new analysis showing consistent efficacy and safety with AR101 across the phase 3 PALISADE and ARTEMIS trials, despite differing regions of study, entry criteria, therapeutic dosing periods and primary efficacy endpoints. The data were presented at the American College of Asthma, Allergy and Immunology (ACAAI) Annual Scientific Meeting in Houston.

The study comparison found substantially and significantly higher proportions of AR101-treated patients were able to tolerate clinically meaningful quantities of peanut protein compared to patients in the placebo arm at the double-blind, placebo-controlled food challenge (DBPCFC) that occurred at the end of the study. Overall safety was similar between the two patient populations, and the frequency of adverse events decreased in the fixed therapeutic dosing period compared to the dose escalation period.

“I’m encouraged to see that, across two robust and rigorously conducted clinical trials, the efficacy and safety of AR101 was consistent showing that treatment resulted in patients tolerating higher quantities of peanut protein while also confirming that the frequency of adverse events – while mostly mild or moderate – decreased during the therapeutic dosing period across both studies,” said Ellen R. Sher, MD, study author and an allergist and immunologist with Allergy Partners of New Jersey, Section Chief of Allergy and Immunology at Monmouth Medical Center in Long Branch, NJ, and a Clinical Assistant Professor of Medicine at Rutgers Robert Wood Johnson Medical School in Piscataway, NJ. “As an allergist, I understand the importance of carefully discussing with patients and parents whether OIT is right for them and that it can be tailored to their needs. The similarities between the PALISADE and ARTEMIS trials provide important insights regarding the clinical potential of AR101 in treating a variety of patients, regardless of geographic location and other factors we take into consideration.”

Across both studies:

- The median tolerated dose of peanut protein increased from 10 mg to 1000 mg between the entry and exit food challenges.
- Approximately two-thirds of patients tolerated 600 mg and over half tolerated 1,000 mg in the exit food challenge.
- Treatment emergent adverse events (TEAEs) that arose during in-clinic dose escalation visits occurred shortly after dose administration – typically within 30 minutes – and were transient in nature, generally resolving within 60 minutes.
- The frequency of TEAEs decreased in the therapeutic 300 mg/day AR101 dosing period compared with the dose escalation period.

One observed difference between the two studies was the use of epinephrine to treat TEAEs. In PALISADE, approximately 14.0% of patients were administered epinephrine whereas in ARTEMIS, 6.8% of the patients were administered epinephrine, probably reflecting practice differences between the United States and Europe.

AR101 is an investigational biologic drug for use during oral immunotherapy to reduce the incidence and severity of allergic reactions following exposure to peanuts. The Biologics License Application (BLA) for AR101 is under review by the 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.

About PALISADE

The international, randomized, double-blind, placebo-controlled phase 3 PALISADE (Peanut Allergy oral Immunotherapy Study of AR101 for Desensitization) 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 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.

About ARTEMIS
The randomized, double-blind, placebo-controlled phase 3 ARTEMIS (AR101 Trial in Europe Measuring oral Immunotherapy Success) trial evaluated the efficacy and safety of AR101 in peanut-allergic patients ages 4 to 17 years who were enrolled at 18 sites in seven European countries
(France, Germany, Ireland, Italy, Spain, Sweden and the United Kingdom). A total of 175 children and adolescents were randomized 3:1 to AR101 or placebo. Study participants represented a highly allergic population with a high prevalence of comorbidities who reacted to low doses of peanut protein when given a DBPCFC at screening. Study participants received approximately six months of dose escalation and then three months of therapeutic dosing of AR101 300 mg/day or placebo, followed by an exit DBPCFC. The primary endpoint was the patient's ability to tolerate at least a 1,000 mg single dose of peanut protein (the equivalent of approximately three to four peanut kernels) without dose-limiting symptoms when given the DBPCFC.

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: 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191108005169/en/

Source: Aimmune Therapeutics, Inc.

Investors:
DeDe Sheel
(917) 834-1494
dsheel@aimmune.com

Media:
Lauren Barbiero
(646) 564-2156
lbarbiero@w2ogroup.com

---

https://swkhold.investorroom.com/2019-11-08-AR101-Demonstrates-Consistent-Efficacy-and-Safety-in-New-Analysis-at-ACAAI-Comparing-PALISADE-and-ARTEMIS-Phase-3-Clinical-Data