Aimmune Therapeutics Discusses AR101's Cost-Effectiveness and Demonstrated Clinical Benefits at ICER Meeting

Company to Share Updated Clinical Data on AR101 and Provide Perspective on Its Value to Society

BRISBANE, Calif.--(BUSINESS WIRE)--Jun. 11, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, will present at the Institute for Clinical and Economic Review's (ICER) Public Meeting reviewing the effectiveness and value of treatments for peanut allergy, to be held today in Oakland, California. Aimmune is developing AR101, 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.

Cost per QALY, or quality-adjusted life year, measures the economic value of a health care intervention; the lower the cost per QALY, the higher the value of the treatment. Using only clinical data from the landmark Phase 3 PALISADE trial, ICER found AR101 to be cost-effective well-below ICER's traditional threshold of $100,000-$150,000 per QALY. Additionally, when factoring in the societal perspective, ICER found AR101 to be even more cost-effective compared to avoidance alone. This early analysis does not include recent efficacy and safety data from the Phase 3 ARTEMIS trial or long-term patient reported outcomes.

"We are committed to delivering AR101 to patients and families with peanut allergy, and we look forward to providing our perspective at today's meeting about the important value AR101 will provide to patients, payers, healthcare systems and society as a whole," said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune. "We have been working collaboratively with ICER over the last eight months to provide data about the strong value proposition of AR101 which, if approved, will be the first-ever treatment for peanut allergy."

Peanut allergy is one of the most common food allergies, affecting more than 1.6 million children and teens in the United States.1 It can be a chronic and life-long condition, and symptoms from accidental exposures to peanut are often severe and potentially life-threatening.2 The threat of a severe reaction dominates families' daily lives and interferes with their quality of life.

Stephen Tilles, M.D., Senior Director of Medical Affairs, will represent Aimmune at today's meeting. A board-certified allergist and immunologist and recent past president of the American College of Allergy, Asthma and Immunology (ACAAI), Dr. Tilles will discuss the critical need for rigorously developed, clinically tested, approved treatment for peanut allergy.

In his statement, Dr. Tilles will note that, "For more than 20 years, as the peanut allergy epidemic has continued to grow, I have shared in the sadness and frustration of young patients and their families about the lack of any approved options for treatment. Avoidance has ruled the day – but it is the opposite of a patient-centered treatment because it often prevents children from living a normal childhood. For example, data from a new study found that 40% of teens believe they have a high likelihood – and some believe a certainty – of dying from an accidental exposure to peanuts. Avoiding peanuts in the real world is a difficult and ineffective way of managing peanut allergy. Accidental exposures are inevitable, traumatic – and can be fatal. With this in mind, Aimmune has deployed an oral immunologic approach that uses defined, precise amounts of key allergens to address the broad spectrum of scenarios that could cause exposure."

New data released at the 2019 European Academy of Allergy and Clinical Immunology (EAACI) Congress reinforce the clinical profile of AR101 and demonstrate improved safety and immunomodulation with continued longer-term daily treatment.

Dr. Dallas added, "While Aimmune has provided ICER with additional evidence to support an accurate evaluation of AR101, data continue to emerge suggesting improved efficacy and decreased adverse effects over time. This pattern is identical to subcutaneous immunotherapy for pollen allergy and stinging insect allergy, both of which have been shown to result in disease modification after three to five years of therapy. Therefore, although ICER finds AR101 to be cost-effective well within standard thresholds, we believe the value estimates for AR101 in ICER's evidence report are overly conservative, especially as the potential for disease modification was not considered."

The FDA's Allergenic Products Advisory Committee (APAC) will review Aimmune's Biologics License Application (BLA) for AR101 at its meeting scheduled for September 13, 2019. The FDA accepted the BLA for AR101 in March 2019 and previously informed Aimmune that completion of its review would be targeted by late January 2020. The FDA granted AR101 Fast Track Designation in September 2014 and Breakthrough Therapy Designation in June 2015 for peanut-allergic children and adolescents ages 4 to 17.

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 characterized protein profile, analyzed to ensure consistent 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 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 its presentation at the ICER meeting and statements made by Aimmune representatives at such meeting; Aimmune's expectations regarding the potential benefits of AR101, including the potential benefit of continued therapy; Aimmune's expectations regarding the overall value of therapy with AR101, including the value estimate of AR101 made by ICER; 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.

1 Aimmune market research.

2American College of Allergy, Asthma & Immunology. Available here: https://acaai.org/allergies/types/food-allergies/types-food-allergy/peanut-allergy. Accessed May 15, 2019.

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