New Real-World Data Unveiled at ACAAI Indicates Comparable Clinical Practice Logistics to Implement Oral Immunotherapy and Environmental Allergy Shots

HOUSTON--(BUSINESS WIRE)--Nov. 8, 2019-- Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today revealed that the logistical needs for implementing oral immunotherapy (OIT) for food allergies, such as peanut allergy, into clinical practice is comparable to those for subcutaneous immunotherapy (SCIT) for environmental allergies. These data were presented at the American College of Asthma, Allergy and Immunology (ACAAI) Annual Scientific Meeting in Houston.

“As more and more allergists consider incorporating OIT into their clinical practice as a potential treatment approach for people with food allergies, it’s important that the implementation can be seamless from a logistical perspective and enable allergists to continue to deliver personalized care, similar to what they’re familiar with when performing environmental allergy shots which are already part of their established practice,” said Joel M. Hartman, MD, study author and physician owner at Allergy Partners, the largest single-specialty allergy practice in the U.S. focusing on treating asthma and allergic disease with locations across 20 states. “We believe allergists and immunologists who are considering adding OIT to their practices for food allergy will be pleased to hear the results from the survey, as it proves to be a similar implementation process to the age-old and widely accepted approach currently used for allergies such as mold, dust, grass/weeds and animal dander.”

In a double-blinded, self-administered online survey of 80 allergists and immunologists who prescribe both OIT and SCIT, patterns of effective clinical practice logistics showed that the ratio of clinical staff to providers was generally comparable for administering both approaches, with the majority of respondents reporting ratios of either 2:1 or 3:1 of clinical staff to providers. While the staffing needs for SCIT were somewhat greater than those for OIT, they varied based on the volume of patients treated.

Additional study findings suggest that the number of needed exam rooms also varied based on patient volume. The majority of OIT patient needs were met with either one room set aside or by using general allergy care exam rooms. Nearly 60% of physicians indicated that the duration of the patient consent process differed for food OIT and environmental SCIT, with about 90% of those reporting that the consent process for SCIT is shorter than for food OIT. However, the survey also highlights that efficient modules for patient education may provide for more streamlined informed consent processes.

OIT involves retraining the immune system by introducing small doses of an allergen into an individual’s diet and gradually building up to larger amounts over time. Under the close supervision of a trained allergist, patients ingest small amounts of the allergen, which is then steadily increased over time. The goal is to gradually desensitize the patient to the allergen, thus reducing the likelihood of a severe allergic reaction in the event the patient accidently ingests the allergen. Once they reach the therapeutic dose of the OIT treatment, patients will continue to take a daily dose to maintain desensitization. Despite the promise of OIT in treating patients with food allergies, there are currently no guidelines on how to implement OIT into clinical practice to encourage widespread adoption.

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 reaction to study results regarding implementation of OIT in clinical practice, the OIT process for desensitization, 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.

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Source: Aimmune Therapeutics, Inc.

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

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