New Study Shows More Than Half of Teens with Peanut Allergy Visited the E.R., More Than One-Third Required Hospitalization Due to Accidental Exposure to Peanut

-- 4 in 10 Teens believe they have a great or very great chance or certainty of dying from accidental exposure --

NEW ORLEANS--(BUSINESS WIRE)--May 21, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced results of a new study of U.S. adolescents with peanut allergy that found more than half required a visit to the emergency room or urgent care and one-third required hospitalization as a result of peanut exposure in the past 12 months, despite the fact that 100% of those surveyed reported actively avoiding peanut products. The study findings were presented here today in a poster session at the International Society for Pharmacoeconomics Outcomes Research (ISPOR) 2019 Annual Meeting in New Orleans.

“These results illustrate how peanut avoidance, in practical day-to-day terms, provides neither the protection nor the confidence that patients are able to appropriately manage their disease in the real world,” said William McCann, M.D., senior author and Director, Vice President and Chief Medical Officer of Allergy Partners, the large single-specialty allergy practice in the U.S., focusing on treating asthma and allergic disease with locations across 20 states. “In addition to the urgent medical interventions that are required, these findings elucidate the anxiety felt by these adolescents who live in daily fear of accidental exposure, respiratory distress and even death. Clearly, the strategy of avoidance is not working given the amount of medical interventions these teens require. New options are needed for these patients to help alleviate the constant fear and serious consequences of accidental exposures.”

Study Design

The study, titled “Real-World Experience of Peanut-Allergic Adolescents in the United States: Health-Related Concerns and Resource Utilization for Peanut Allergy” (abstract #PRS60), was conducted to better understand the experience of peanut allergic adolescents and their use of healthcare resources to manage peanut allergy and health-related concerns. The study recruited 102 adolescents ages 13 to 17 (mean age: 14.7 years) with self-reported, physician-diagnosed peanut allergy using commercial research panels. Study participants took an online survey, which included the Food Allergy Independent Measure (FAIM) to assess perceived risk and expectations of allergy outcomes.

Study Results
Key findings were as follows:

Use of Healthcare Resources for Peanut Allergy in Past Year

- 57% of respondents required at least one visit to an emergency room or urgent care facility and 37% required at least one hospitalization stay of overnight or longer as a result of peanut exposure, despite 100% of survey participants saying they actively avoided peanut products.
- 55% reported at least one unscheduled visit to an allergist due to a reaction.
- 60% reported at least one use of an epinephrine autoinjector and 27% reported needing an epinephrine autoinjector without having access to one.

Health-Related Concerns of Peanut Allergy

- 35% of respondents said they felt “not at all confident,” “not very confident” or “somewhat confident” managing peanut allergy reactions.
- 44% of respondents said they felt “not at all in control,” “not very much in control” or “somewhat in control” of their peanut allergy despite the fact that 93% had been prescribed an epinephrine autoinjector (with 88% carrying it 75% or more of the time), and 100% said they actively avoided peanut products.
- 46% reported physical symptoms experienced during a reaction as the most concerning aspect of peanut allergy, with respiratory symptoms considered the most worrisome (reported by 75%). Other concerning aspects were having quick access to needed care (25%), impact on social interactions (10%), impact on mental health (10%), and impact on family (9%).
- 40% of respondents said there was a “great chance,” “very great chance” or a “certainty” of death resulting from accidentally eating something to which they were allergic.

The abstract of the ISPOR 2019 presentation can be found at www.ispor.org, and the poster presentation can be found in the News & Events section of Aimmune Therapeutics’ website at www.aimmune.com.

About Peanut Allergy

Peanut allergy, a common type of food allergy, has become increasingly prevalent in recent years, particularly among children (Sicherer 2010). Recent claims-based data suggest that approximately 2.2% of all children and adolescents in the United States (1.25 million) have peanut allergy (Lieberman 2018). Individuals with peanut allergy who are exposed to peanuts can develop various allergic symptoms that range in severity and onset. The most severe systemic allergic reaction is anaphylaxis, which may be life-threatening and requires immediate treatment with epinephrine (Boyce 2010). Currently, no curative treatments exist for peanut allergy, and recommended management strategies include avoiding peanuts and appropriately treating symptoms of a reaction (Boyce 2010; Sitton 2018). Given the potential severity of symptoms and need for close management, living with food allergies such as peanut allergy present day-to-day concerns and challenges for allergic individuals and their families (Cummings 2010), and contribute to increased healthcare resource utilization and economic burden (Gupta 2013).

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 the potential benefits of AR101; Aimmune's expectations regarding the review of the BLA for AR101; 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: the expectation that Aimmune will need additional funds to finance its operations; 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.

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