Aimmune Enrolls First Patient in Phase 2 Trial of AR201 for Egg Allergy

BRISBANE, Calif.--(BUSINESS WIRE)--Aug. 21, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced that it has randomized its first patient in a phase 2 clinical trial of AR201 for the treatment of egg allergy. AR201, an investigational biological drug for use in oral immunotherapy for egg allergy, is the second development program that Aimmune is advancing to phase 2 using its Characterized Oral Desensitization ImmunoTherapy (CODIT™) platform.

Egg allergy is a common and serious condition that disproportionately affects children and can be associated with severe hypersensitivity reactions, including life-threatening anaphylaxis. Nearly 6 million people worldwide are allergic to eggs, including 800,000 in the U.S. and as many as 4 million across Asia, where allergy to egg is the most common food allergy.

Currently, there are no approved treatments for egg allergy. The standard of care for managing egg allergy is avoiding eggs in the diet and educating patients and families to recognize and manage allergy symptoms. In some cases, rescue medications, including epinephrine auto-injectors, are necessary. However, avoidance of egg is exceptionally challenging for individuals with egg allergy because of the ubiquity of egg as an ingredient in many food products, and accidental exposure to egg is common.

“The initiation of our first phase 2 clinical trial of AR201 in children, adolescents and young adults with egg allergy marks an important milestone toward our goal of being the leader in the development and delivery of approved treatments for food allergy,” said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune. “In developing AR201, we hope to help alleviate the constant fear of accidental exposure, which can have a significant negative impact on quality of life for egg-allergic patients and their families.”

The Company’s first development program to use CODIT is 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 peanut.

About the AR201 Phase 2 Clinical Trial

The randomized, double-blind, placebo-controlled phase 2 study is evaluating the efficacy and safety of AR201 oral immunotherapy for desensitization in patients ages 4 to 26 years with hen egg allergy. Eligible patients who develop dose-limiting allergy symptoms after consuming single doses of ≤300 mg dried egg white protein in a screening double-blind, placebo-controlled food challenge (DBPCFC) will be randomly assigned 2:1 to blinded treatment with AR201 or placebo. The study will use a standardized method for oral immunotherapy with AR201 that will consist of initial dose escalation at low doses, gradual dose escalation over time to limit allergic reactions (escalating one dose level every two weeks), and fixed therapeutic dosing at 300 mg/day dried egg white protein. The trial is expected to enroll approximately 84 patients at approximately 15 sites in the U.S.

The primary efficacy endpoint is the proportion of patients treated with AR201 compared with placebo who tolerate a single highest dose of at least 1,000 mg dried egg white protein with no more than mild allergy symptoms at the exit DBPCFC. Secondary efficacy endpoints include the proportion of patients who tolerate a single highest dose of at least 300 mg dried egg white protein with no more than mild allergy symptoms during the exit DBPCFC; the proportion of patients who tolerate a single highest dose of at least 600 mg dried egg white protein with no more than mild allergy symptoms during the exit DBPCFC; and the maximum severity of allergy symptoms after consuming dried egg white protein during the exit DBPCFC.

About AR201

AR201 is an investigational biological drug in clinical development for use in oral immunotherapy for egg allergy. Academic studies of the oral immunotherapy approach for egg allergy treatment have shown efficacy, and Aimmune is studying this more broadly with AR201 in order to enable widespread availability of a potential treatment.

Aimmune has an exclusive supply agreement for egg protein with Michael Foods, Inc., the largest U.S. processor of value-added eggs. The agreement includes all of the company’s egg products, worldwide, and gives Aimmune exclusive access to the clinical and commercial use of Michael Foods egg products for any egg allergy treatment, prevention or cure for a period of up to 15 years beyond the potential approval of AR201.

About Aimmune

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, complex biologic product, AR101, is being developed as a treatment to reduce the frequency and severity and adverse events following exposure to peanut. The BLA for AR101 is under review by the FDA, which granted AR101 Breakthrough Therapy Designation in 2015 for the desensitization of peanut-allergic patients 4 to 17 years of age. The Allergenic Products Advisory Committee (APAC) of the FDA will review the BLA for AR101 at its meeting scheduled for September 13, 2019. Aimmune initiated a randomized phase 2 clinical trial of 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 AR201 for egg allergy, including quality of life improvements and relief from the fear of accidental exposure; Aimmune's expectations regarding the purpose, characteristics and methodology of the AR201 Phase 2 clinical trial; Aimmune's expectations regarding enrollment in the AR201 trial; Aimmune's expectations regarding the timing of the review of the BLA for AR101 by the FDA and APAC; 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 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 June 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 AR201 and AR101, product candidates that are under clinical investigation. Neither AR201 nor AR101 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/20190821005232/en/

Source: Aimmune Therapeutics, Inc.

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

Media:
Jerica Pitts
(312) 858-3469
jpitts@w2ogroup.com
