Aimmune to Present AR101 Data at European Academy of Allergy and Clinical Immunology 2019 Congress

– Full Results from Phase 3 ARTEMIS Study Will Be Featured –

BRISBANE, Calif.--(BUSINESS WIRE)--May 24, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced that it will present AR101 and patient quality of life data at the European Academy of Allergy and Clinical Immunology (EAACI) 2019 Congress, taking place June 1 to 5, 2019, in Lisbon, Portugal. Of the six abstracts accepted by EAACI, three are oral presentations and one is a late-breaker poster presentation.

“We are eager to present the full topline results from our Phase 3 ARTEMIS trial, which further support the evidence we first showed with our PALISADE and RAMSES studies that AR101-treated patients can expect to achieve a clinically meaningful level of desensitization,” said Daniel Adelman, M.D., Chief Medical Officer of Aimmune. “We believe that the positive results from our entire AR101 Phase 3 program, which we also will be discussing during the meeting, demonstrate that AR101 has a consistent benefit-risk profile. In addition, we are also pleased to be presenting data that underscore the real-world effects of living with peanut allergy as reported by patients themselves.”

The data will be presented as follows:

Oral Presentations

Title: ARTEMIS: A European, Phase 3, Randomised, Double-Blind, Placebo-Controlled Trial of AR101 In Peanut-Allergic Children And Adolescents Aged 4-17 (abstract OA0023)
Presenter: Montserrat Fernandez-Rivas, M.D., Hospital Clinico San Carlos, Madrid, Spain
Session Title: Oral Abstract Session 04: Outcome measures in allergen and immunotherapy
Date/Time: Sunday, June 2, 2019 / 11:32 a.m. to 11:44 a.m. (WEST) / 6:32 a.m. to 6:44 a.m. (ET)
Location: Hall 13 (FIL)

Title: Extended Daily Dosing of AR101 For Peanut Allergy Results in Higher Tolerated Doses And Continued Immunomodulation (abstract OA0120)
Presenter: Katharina Blümchen, M.D., University Hospital Frankfurt, Frankfurt, Germany
Session Title: Oral Abstract Session 21: Treatment of food allergy
Date/Time: Tuesday, June 4, 2019 / 10:42 a.m. to 10:52 a.m. (WEST) / 5:42 a.m. to 5:52 a.m. (ET)
Location: Hall 8 (FIL Meeting Centre)

Title: Improvement in Disease-Specific Quality of Life for Peanut-Allergic Subjects Receiving AR101 Maintenance Therapy (abstract OA0166)
Presenter: Jonathan Hourihane, M.D., University College Cork, Cork, Ireland
Session Title: Oral Abstract Session 28: Achieving tolerance and better quality of life in food allergic patients
Date/Time: Tuesday, June 4, 2019 / 2:32 p.m. to 2:44 p.m. (WEST) / 9:42 a.m. to 9:44 a.m. (ET)
Location: Hall 13 (FIL)

Poster Presentations

Title: Allergy to Peanut ImPacting Emotions and Life (APPEAL) 2: The First European Multi-Country Qualitative Evaluation of the Impact of Living with Peanut Allergy. (late breaking poster LBPD1761)
Presenter: Audrey Dunn Galvin,Ph.D., University College Cork, Core, Ireland
Session Title: Late Breaking Poster Discussion Sessions 04 Food Allergy: Cutting-edge concepts
Date/Time: Monday, June 3, 2019 / 1:45 p.m. to 3:15 p.m. (WEST) / 8:45 a.m. to 10:15 a.m. (ET)
Location: PDS Dome in e-Poster Area D (FIL)

Title: Real-World Experience and Management of Peanut Allergy: A Quantitative Study of Adolescents With Peanut Allergy In The United States (e-poster PD0550)
Presenter: Christine Birchwood, Ph.D., Sr. Director, Interim head, Medical Affairs at Aimmune Therapeutics
Session Title: Poster Discussion Session 26: Management of food allergy
Date/Time: Tuesday, June 4, 2019 / 1:10 p.m. to 3:00 p.m. (WEST) / 8:10 a.m. to 10 a.m. (ET)
Location: PDS Dome in e-Poster Area (FIL)

Title: Baseline Demographics of >1100 Peanut-Allergic Subjects Aged 4-17 Years Randomised in Three Double-blind Placebo-controlled Phase 3 AR101 Trials: PALISADE, RAMSES and ARTEMIS (e-poster PD0548)
Presenter: Kirsten Beyer, M.D., Charité Universitätsmedizin Berlin, Berlin, Germany
Session Title: Poster Discussion Session 26: Management of food allergy

Date/Time: Tuesday, June 4, 2019 / 1:30 p.m. to 3:00 p.m. (WEST) / 8:30 a.m. to 10 a.m. (ET)
Location: PDS Dome in e-Poster Area (FIL)

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, including anaphylaxis, 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 presentation of AR101 data at the 2019 European Academy of Allergy and Clinical Immunology Congress, including data from the ARTEMIS trial and regarding patient quality of life; Aimmune's expectations regarding the potential benefits of AR101; Aimmune's expectations regarding the potential commercial launch of AR101, including the review period 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; 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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Source: Aimmune Therapeutics, Inc.

Investors:
Eric Bjerkholt
(650) 376-5582 or
ebjerkholt@aimmune.com

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

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