Aimmune Statement on Institute for Clinical and Economic Review (ICER) Final Report on AR101 for Peanut Allergy

Exclusion of long-term desensitization and patient quality-of-life data by ICER fails to recognize the full value AR101 immunotherapy can deliver to the peanut allergy community

BRISBANE, Calif.--(BUSINESS WIRE)--Jul. 11, 2019-- Aimmune Therapeutics (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, cautions stakeholders against drawing conclusions from the Institute for Clinical and Economic Review's (ICER's) final report on emerging desensitization treatments for peanut allergy, released yesterday. In its review, ICER fails to incorporate available data on both long-term outcomes and quality-of-life. ICER's analysis and the public meeting discussion discounted patient and community perspectives on the physical, social and psychological benefits of desensitization.

The resulting final report is biased against immunotherapy, generally, and fails to specifically capture the full value of AR101. Aimmune joins advocates and clinical experts asking payers and policymakers to engage in more thoughtful, unbiased consideration of available evidence—including patient perspectives on quality-of-life improvements and relief from the stress and fear of accidental exposure—when evaluating emerging treatments for peanut allergy.

In clinical trials, AR101, Aimmune's investigational biologic drug for use in oral immunotherapy, has demonstrated the ability to increase the median tolerated dose of peanut protein by 100-fold in each of its two pivotal Phase 3 clinical trials. While the report found AR101 to be cost-effective well below traditional health economic thresholds, ICER failed to acknowledge the availability of the positive long-term efficacy and quality-of-life data from the PALISADE open label follow-on study, as well as the clinical outcomes data from the European Phase 3 ARTEMIS trial. These data were recently presented at the 2019 European Academy of Allergy and Clinical Immunology (EAACI) Congress and shared with ICER in May under its "academic in confidence" policy and throughout the review process including the June 11 public meeting. ICER did not acknowledge or incorporate the existing data in its final evidence report or the associated cost-effectiveness analysis.

"From the onset, we have believed that ICER's attempt to assess the value of AR101 was premature, based too heavily on theoretical discussions rather than real-world insight, and omitted valuable patient perspective. Critical data from our Phase 3 trial program continues to emerge, specifically new patient-reported quality-of-life data that were excluded from the analysis," said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune. "We believe this final report raises more questions than it answers and should be viewed as an early starting point for future conversations—not the final word—about the value of AR101."

Additionally, ICER failed to consider the potential for long-term disease modification consistent with allergen immunotherapies and mischaracterized the allergic response associated with immunotherapy as a harm, rather than an expected, well understood and easily managed part of the immunotherapy process. With all immunotherapy, allergic reactions are expected and acceptable in the short term in exchange for long-term desensitization to protect against accidental exposure. In clinical trials, median tolerated dose for AR101-treated patients improved from 10mg at baseline to 1000mg at month 12 to 2000mg at month 18—demonstrating both the potential for long-term disease modification and the potential for significant protection against the average real-world reaction-provoking exposure of 125mg, or half a peanut.

"The peanut allergy community, including patients, families, advocates and allergists, are well aware of and well prepared for the possibility of reactions as part of the shared decision-making process involved in immunotherapy," said Stephen Tilles, M.D., Senior Director of Medical Affairs at Aimmune, and a nationally recognized 20-plus-year clinical expert who represented Aimmune at ICER's public meeting. "Not every patient has a reaction with immunotherapy, but patients and families live every day with fear and anxiety of unpredictable, potentially life-threatening reactions due to accidental exposure. If approved, AR101 will offer patients the potential for meaningful desensitization using a clinically developed, rigorously-tested treatment in close collaboration with their allergists."

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. In June 2019, Aimmune submitted a Marketing Authorization Application to the European Medicines Agency (EMA) for AR101. 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, including quality-of-life improvements and relief from the stress and fear of accidental exposure; Aimmune's expectations regarding the potential ability of AR101 to effect meaningful desensitization, long-term disease modification and significant protection against real-world exposure; Aimmune's expectations regarding the timing and completion of the review of the BLA for AR101 by the FDA and APAC; 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 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

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

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

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