Aimmune Submits Marketing Authorization Application to European Medicines Agency for AR101 for Peanut Allergy

BRISBANE, Calif.--(BUSINESS WIRE)--Jun. 28, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for AR101, an investigational biologic oral immunotherapy to reduce the frequency and severity of allergic reactions following exposure to peanuts in children and adolescents ages 4 to 17.

“This is an important milestone for us as a company, as well as for people across Europe living with peanut allergy, a growing worldwide health problem that significantly affects the quality of life of both patients and their families,” said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune. “We are continuing to expand our organization across Europe to prepare for potential approval of AR101 in key markets and engaging in reimbursement discussions to expedite access for patients upon approval.”

The MAA submission includes extensive data from the only Phase 3 clinical trial program to meet the primary endpoints in children and teens with peanut allergy. This program included well over 1,000 patients enrolled into the PALISADE, RAMSES and ARTEMIS trials. The pivotal European Phase 3 ARTEMIS study, which represents a key component of the MAA submission, reinforced the consistent clinical profile of AR101 after six months of dose escalation and a three-month therapeutic dosing phase. The ARTEMIS trial enrolled 175 peanut-allergic children and adolescents ages 4 to 17 from 18 sites in France, Germany, Ireland, Italy, Spain, Sweden and the United Kingdom.

A Biologics License Application (BLA) seeking approval for AR101 for the treatment of children and adolescents with peanut allergy currently is under review by the U.S. Food and Drug Administration (FDA), which is expected to take until late January 2020. The Allergenic Products Advisory Committee (APAC) of the FDA will review the BLA for AR101 at its meeting scheduled for September 13, 2019.

About Peanut Allergy
Peanut allergy is one of the most common food allergies, which affect over 17 million people in Europe.[1] The prevalence of peanut allergy in Europe has doubled between 2005 and 2015, and around two-thirds of schools in Europe currently have at least one child at risk of anaphylaxis.1,2 Reactions to peanut are potentially life-threatening, accounting for the majority of deaths related to food allergy.3 Peanut allergy usually persists into adulthood4,5,6, 7 and there are currently no approved treatment options.8 The standard of care has been a strict elimination diet and the timely administration of rescue medications in case of an allergic reaction from accidental exposure.9,10,11 Despite vigilance, accidental exposures may occur12 and cause reactions of unpredictable severity,13 leading to a lifelong risk of severe reactions.

About AR101
AR101 is an investigational, peanut-derived, 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 consistent protein profile, analyzed to ensure reliable 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. 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 FDA's review period of the BLA for AR101, including the timing of the advisory committee meeting; Aimmune's expectations on the timing of initiating a phase 2 clinical trial for AR201; Aimmune's expectations regarding its expansion in Europe; and Aimmune's expectations regarding potential protections provided by 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 possibility 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.

References

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

EU Media:
Louise Strong
+44 7747-477509
lstrong@w2ogroup.com

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

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