U.S. FDA Accepts BLA Filing of Aimmune Therapeutics' AR101 for Peanut Allergy

-- If Approved, AR101 Will Be the First Medicine for This Life-Threatening Condition --

BRISBANE, Calif.--(BUSINESS WIRE)--Mar. 18, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced that the Biologics License Application (BLA) for AR101 has been accepted for review by the U.S. Food and Drug Administration (FDA).

"Today is a significant milestone for Aimmune. The FDA's acceptance of our BLA is a crucial step forward in delivering AR101 to children, teens and families living with the serious, daily risk of allergic reactions to accidental exposure to peanuts," said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune. "We are working with the FDA to complete their review as expeditiously as possible given that there are currently no approved medicines for peanut allergy."

Aimmune is developing AR101 as a treatment to reduce the risk of anaphylaxis following accidental exposure to peanut. The FDA granted AR101 Breakthrough Therapy Designation in June 2015 for peanut-allergic children and adolescents ages 4-17, which was preceded by the granting of Fast Track Designation in September 2014. Both of these programs support expedited review of new drugs and biologics.

The FDA has informed Aimmune that the BLA will be reviewed under a twelve-month target review period, as measured from the January 2019 start date. As a consequence, review of the BLA may take until late January 2020. Aimmune is currently engaged in discussions with the FDA regarding the review timeline for the AR101 BLA. The FDA expects to convene an advisory committee meeting to discuss the application.

"Every day in the United States, more than one million children and teens with peanut allergy are at risk that exposure to food allergens could lead to potentially life-threatening reactions," said Daniel Adelman, M.D., Chief Medical Officer of Aimmune. "Published epidemiologic studies and everyday experiences of this community show that for many, avoidance of peanuts is not enough. There is an urgent need for a rigorously developed, clinically proven medicine like AR101 that can help protect people when accidental exposures do occur."

Aimmune's BLA is comprised of extensive clinical as well as chemistry, manufacturing and controls (CMC) data. Specifically, data from the pivotal phase 3 PALISADE trial of AR101, the largest and only successful phase 3 trial in peanut allergy, were published in the *New England Journal of Medicine* and demonstrated that AR101 treatment resulted in a significant increase in the amount of peanut protein tolerated compared to placebo. The data suggest that AR101-treated patients could expect fewer and less severe reactions to accidental peanut exposures. Data from the phase 3 RAMSES trial confirmed the safety profile of AR101 first observed in the PALISADE study; both trials are part of the application submission.

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 accidental 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 risk of anaphylaxis following accidental exposures to peanut. AR101 has received the FDA's Breakthrough Therapy Designation for the desensitization of peanut-allergic patients 4-17 years of age. Aimmune expects to file for marketing approval of AR101 in Europe 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 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 applicable 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 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 Annual Report on Form 10-K for the year ended December 31, 2018. 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. AR101 has not been approved for marketing by the FDA or the European Medicines Agency (EMA). AR101 is currently limited to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

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