Aimmune Stock Trading Halted Today; FDA Allergenic Products Advisory Committee (APAC) Meeting to Discuss PALFORZIA™ (AR101) for Peanut Allergy

BRISBANE, Calif.--(BUSINESS WIRE)--Sep. 13, 2019-- Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced that NASDAQ has halted trading of the company's common stock. The U.S. Food and Drug Administration (FDA) Allergenic Products Advisory Committee (APAC) is holding a meeting today from 8:30 a.m. to 4:30 p.m. ET to discuss whether efficacy and safety data support licensure of PALFORZIA™ as a treatment to reduce the incidence and severity of allergic reactions, including anaphylaxis, after accidental exposure to peanut in patients 4 through 17 years of age with a confirmed diagnosis of peanut allergy. The briefing materials can be found here on the FDA website.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing oral treatments for potentially 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 candidate, PALFORZIA™ (AR101), is being developed as a treatment to reduce the frequency and severity of adverse events following exposure to peanut. The BLA for PALFORZIA is under review by the FDA, which granted PALFORZIA Breakthrough Therapy Designation in 2015 for the desensitization of peanut-allergic patients 4 to 17 years of age. The European Medicines Agency (EMA) is reviewing Aimmune's Marketing Authorization Application (MAA) for PALFORZIA, which Aimmune submitted in June 2019. Aimmune initiated a randomized phase 2 clinical trial of its second investigational, complex biologic product, 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 PALFORZIA and AR201 for egg allergy; 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;; and possible regulatory developments in the United States and foreign countries. 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 PALFORZIA, product candidates that are under clinical investigation. Neither AR201 nor PALFORZIA has been approved for marketing by the FDA or the EMA. PALFORZIA 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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