# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 25, 2019**

# AIMMUNE THERAPEUTICS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-37519** | **45-2748244** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification Number)** |

**8000 Marina Blvd, Suite 300**
**Brisbane, CA 94005**
**(Address of principal executive offices, including Zip Code)**

**Registrant's telephone number, including area code: (650) 614-5220**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure.**

On March 25, 2019, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing the topline results of its Phase 3 European clinical trial of AR101 for the treatment of peanut allergy, known as ARTEMIS (**AR**101 **T**rial in **E**urope **M**easuring oral **I**mmunotherapy **S**uccess) (the "Press Release"). A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The Company is also hosting an investor conference call at 8:30 AM PT (8:00 AM ET) on Monday, March 25, 2019 to discuss the topline results from the Company's ARTEMIS study of AR101. Conference call information is as follows:

Conference Call Numbers – 1-877-497-1438 (domestic) or 1-262-558-6296 (international); Conference ID# 5157603

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

On March 25, 2019, Aimmune announced that its Phase 3 European clinical trial of AR101 for the treatment of peanut allergy, known as ARTEMIS, met its primary efficacy endpoint. Topline data show that the proportion of AR101-treated patients who tolerated a 1,000-mg dose of peanut protein (2,043 mg cumulative) in a blinded exit challenge after approximately nine months of AR101 treatment was significantly higher ($p<0.00001$) than in the placebo group. Specifically, the median tolerated dose of peanut protein for AR101-treated patients improved 100-fold, from 10 mg at baseline to 1,000 mg at exit. The trial also greatly exceeded a 15% lower-bound of the 95% confidence interval (CI) of the difference between treatment arms for all endpoints.

In addition, the safety profile and completion rate observed in ARTEMIS are consistent with the results seen in previous AR101 clinical trials. Notably, no cases of anaphylaxis or of eosinophilic esophagitis (EoE) were observed. Aimmune plans to present full results in an oral presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Congress in early June.

The randomized, double-blind, placebo-controlled Phase 3 ARTEMIS clinical trial enrolled 175 children and adolescents ages 4 to 17 from 18 sites in France, Germany, Ireland, Italy, Spain, Sweden and the United Kingdom. Patients underwent approximately six months of dose escalation and then three months at a daily therapeutic dose of AR101 at 300 mg or placebo, followed by an exit double-blind, placebo-controlled food challenge. The primary efficacy endpoint was patients' ability to tolerate a 1,000-mg single dose of peanut protein, the equivalent of approximately three to four peanut kernels (2,043 mg cumulative, equivalent to seven or eight peanut kernels).

Based on the results from ARTEMIS, Aimmune intends to submit a marketing authorization application (MAA) for AR101 to the European Medicines Agency (EMA) in mid-2019.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated March 25, 2019. |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**AIMMUNE THERAPEUTICS, INC.**

Date: March 25, 2019

By: /s/ Douglas T. Sheehy

**Douglas T. Sheehy**
**General Counsel and Secretary**

**European Phase 3 Trial of Aimmune Therapeutics' AR101 Meets Primary Endpoint**

*— Company Intends to Submit European MAA in Mid-2019 —*

*— Webcast and Conference Call Today at 8:30 a.m. EDT —*

**BRISBANE, California, March 25, 2019** — Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced that its phase 3 European clinical trial of AR101 for the treatment of peanut allergy, known as ARTEMIS (**AR**101 **T**rial in **E**urope **M**easuring oral **I**mmunotherapy **S**uccess), met its primary efficacy endpoint. Topline data show that the proportion of AR101-treated patients who tolerated a 1,000-mg dose of peanut protein (2,043 mg cumulative) in a blinded exit challenge after approximately nine months of AR101 treatment was significantly higher ($p<0.00001$) than in the placebo group. Specifically, the median tolerated dose of peanut protein for AR101-treated patients improved 100-fold, from 10 mg at baseline to 1,000 mg at exit. The trial also greatly exceeded a 15% lower-bound of the 95% confidence interval (CI) of the difference between treatment arms for all endpoints.

In addition, the safety profile and completion rate observed in ARTEMIS are consistent with the results seen in previous AR101 clinical trials. Notably, no cases of anaphylaxis or of eosinophilic esophagitis (EoE) were observed. Aimmune plans to present full results in an oral presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Congress in early June.

"We are very pleased with the results of the ARTEMIS trial, which demonstrate that AR101 significantly improved the ability of patients to tolerate the 1,000-mg dose of peanut protein in the exit food challenge, which correlates to at least three or four peanuts. This level of protection provides ample buffer beyond a typical bite of a peanut-containing food in the real world," said Jayson Dallas, M.D., President and CEO of Aimmune. "AR101 has the potential to become the first approved therapy for peanut allergy in both the United States and Europe, where up to two percent of children in many countries are affected. If approved, AR101 could significantly reduce their risk of severe, potentially life-threatening reactions to peanut exposures and provide peace of mind to them and their families."

The ARTEMIS findings reinforce the results from the highest level tested in Aimmune's landmark phase 3 PALISADE trial, which found that 50.3% of AR101-treated patients tolerated a single highest dose of 1,000 mg of peanut protein (2,043 mg cumulative) after approximately six months of dose escalation followed by six months at a daily therapeutic dose of 300 mg, compared to 2.4% of placebo patients ($p<0.00001$). Full results from the PALISADE trial were published in November 2018 in the *New England Journal of Medicine*.

“The ARTEMIS data demonstrate that most patients exceeded what we consider to be protective levels well before a full year of treatment. It’s gratifying to see how these data build upon the insights gained throughout the entire AR101 program regarding the desensitization process and the ability of our patients to tolerate relatively large challenge-doses of peanut protein,” said Daniel Adelman, M.D., Chief Medical Officer of Aimmune. “When added to our prior experiences with AR101, these data enable us to better define the time course of the desensitization and on-going immunomodulation processes as treatment continues.”

The randomized, double-blind, placebo-controlled phase 3 ARTEMIS clinical trial enrolled 175 children and adolescents ages 4 to 17 from 18 sites in France, Germany, Ireland, Italy, Spain, Sweden and the United Kingdom. Patients underwent approximately six months of dose escalation and then three months at a daily therapeutic dose of AR101 at 300 mg or placebo, followed by an exit double-blind, placebo-controlled food challenge. The primary efficacy endpoint was patients’ ability to tolerate a 1,000-mg single dose of peanut protein, the equivalent of approximately three to four peanut kernels (2,043 mg cumulative, equivalent to seven or eight peanut kernels).

Based on these positive results, Aimmune intends to submit a marketing authorization application (MAA) for AR101 to the European Medicines Agency (EMA) in mid-2019. Aimmune submitted a biologics license application (BLA) for AR101 to the U.S. Food and Drug Administration (FDA) in December 2018, and its review by the agency began following the end of the U.S. government shutdown in January 2019. The FDA informed Aimmune that the BLA will be reviewed under a 12-month target review period, as measured from the January 2019 start date. Consequently, review of the BLA may take until late January 2020.

**Conference Call**

In connection with this announcement, Aimmune Therapeutics will host a conference call and webcast today at 8:30 a.m. EDT. To access the live call by phone, dial (877) 497-1438 (domestic) or +1 (262) 558-6296 (international) and enter the passcode 5157603. To access a live or recorded webcast of the call, please visit the Investor Relations section of the Aimmune Therapeutics website at www.aimmune.com. The recorded webcast will be available for approximately 30 days following the call.

**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. The BLA for AR101 is under review by the 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 expectations regarding the potential benefits of AR101; Aimmune's expectations regarding 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; Aimmune's plans to present ARTEMIS results at an upcoming conference in Europe; 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, and AR201, a product candidate that Aimmune expects will be under clinical investigation in 2019. Neither AR101 nor AR201 have 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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**Contacts:**

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

**Media:**
Alison Marquiss
(650) 376-5583 or
amarquiss@aimmune.com