Aimmune Therapeutics Announces First Quarter 2019 Financial Results and Provides Operational Highlights

Potential FDA approval of AR101 for peanut allergy expected by late January 2020; Company on target to be launch-ready in Q4 2019
Submission of marketing application for AR101 in Europe on track for mid-2019, following positive topline results of ARTEMIS European Phase 3 trial
Initiation of AR201 phase 2 trial in egg allergy expected in mid-2019
Strong balance sheet expected to fund commercialization of AR101 in the U.S. and Europe and development of pipeline
Webcast and conference call today at 4:30 p.m. ET

BRISBANE, Calif.--(BUSINESS WIRE)--May 8, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced financial results for the quarter ended March 31, 2019. For the quarter ended March 31, 2019, net loss was $54.3 million and cash, cash equivalents, and investments totaled $296.3 million on March 31, 2019.

“We are well on track to introduce AR101 as potentially the first-ever approved treatment for peanut allergy, a significant milestone for our Company, the allergist community, and the millions of people who live with the daily risk of serious reactions to accidental peanut exposure,” said Jayson Dallas, M.D., President and CEO of Aimmune Therapeutics. “The FDA’s acceptance of our BLA was a key step forward and now we continue to work with the FDA to facilitate an expeditious review. In parallel, in the U.S., we are continuing our medical education through our MSL Team and are fully ramping up our commercial efforts and scaling our organization to be launch-ready by Q4 this year. Recent market research has provided additional focus to this effort. For example, we have found that the approximately 30 percent of allergists who are most eager and ready to offer AR101 to their patients, if approved, today see approximately 70 percent of peanut allergic patients.”

Dr. Dallas added: “We also continue to advance efforts toward submitting a marketing authorization application for AR101 to the European Medicines Agency in mid-2019, following our positive ARTEMIS European phase 3 study. We are excited to present the full ARTEMIS results at EAACI in early June. In addition, we expect to initiate a phase 2 trial of AR201 in egg allergy in mid-2019. Moreover, we remain in a strong financial position to commercialize AR101 and advance our pipeline programs.”

AR101 Highlights

- **Biologics License Application (BLA) for AR101 was accepted for review by the U.S. Food and Drug Administration (FDA)**. In March 2019, the FDA accepted for review the BLA for AR101 for the treatment of peanut allergy in children and adolescents ages 4 to 17, which Aimmune had submitted to the agency in December 2018. 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. Review of the BLA may therefore take until late January 2020. The FDA expects to convene an advisory committee meeting to discuss the application.
- **Positive phase 3 ARTEMIS topline data announced; submission of marketing authorization application (MAA) to European Medicines Agency (EMA) on track.** In March 2019, the Company announced that the phase 3 ARTEMIS European clinical trial of AR101 for the treatment of peanut allergy in children and adolescents ages 4 to 17 met its primary efficacy endpoint. Topline data showed 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. 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 the primary endpoint. The safety profile and completion rate observed in ARTEMIS were consistent with results seen in previous AR101 clinical trials, and no cases of anaphylaxis or eosinophilic esophagitis (EoE) were observed. Aimmune intends to submit a MAA for AR101 to the EMA in mid-2019. Aimmune also plans to present full results of the ARTEMIS trial in an oral presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Congress on June 2, 2019.

POSEIDON trial and AR101 with adjunctive dupilumab trials ongoing. In December 2018, Aimmune initiated its phase 3 POSEIDON trial to explore the efficacy and safety of AR101 in young peanut-allergic children, ages 1 to 3. In October 2018, a phase 2 trial of AR101 with adjunctive dupilumab was initiated in peanut-allergic patients. Regeneron is the trial’s sponsor, and Aimmune is supplying AR101 clinical trial material.

AR201 Highlights

- **Phase 2 trial initiation on track for mid-2019.** Aimmune's Investigational New Drug (IND) application for AR201 was cleared by the FDA, as previously announced, and the Company remains on track to begin a phase 2 trial in egg allergy in mid-2019.

Upcoming Milestones

Mid 2019	Initiate phase 2 clinical trial of AR201 in egg allergy
Mid 2019	Submit Marketing Authorization Application for AR101 to the European Medicines Agency
Second Half of 2019	Potential FDA Advisory Committee meeting to review AR101 BLA
Jan 2020	Potential FDA approval of AR101 for the treatment of peanut allergy in children and adolescents ages 4 to 17
Q1 2020	Potential U.S. commercial launch of AR101

First Quarter Financial Results

For the quarter ended March 31, 2019, net loss was $54.3 million, compared to net loss of $49.5 million for the comparable period in 2018.

On a per share basis, net loss for the quarter ended March 31, 2019, was $0.87, compared to net loss per share of $0.92 for the comparable period in 2018. The weighted average shares outstanding for the quarter ended March 31, 2019, were 62.0 million, compared 53.6 million shares for the comparable period in 2018.

Research and development expenses for the quarter ended March 31, 2019, were $31.3 million, compared to $33.4 million for the comparable period in 2018. The decrease was primarily due to lower costs from the progression of certain AR101 clinical trials offset by higher contract manufacturing costs to support clinical development and regulatory activities.

General and administrative expenses for the quarter ended March 31, 2019, were $23.7 million, compared to $16.7 million for the comparable period in 2018. The increase was primarily due to additional employee-related costs and external professional services as Aimmune continued to build its infrastructure to support the development and potential commercialization of AR101.

Cash, cash equivalents, and investments totaled $296.3 million on March 31, 2019, compared to $303.9 million on December 31, 2018. The decrease primarily reflects net cash used in operating activities of $45.8 million partially offset by cash provided by financing activities, including net borrowings from our debt issuance in January 2019 of $36.1 million.

Conference Call

In connection with this announcement, Aimmune Therapeutics will host a conference call and webcast today at 4:30 p.m. ET. To access the live call by phone, dial (877) 497-1438 (domestic) or (262) 558-6296 (international) and enter the passcode 5667779. 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 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 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 potential commercial launch of AR101, including 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 expectations on the planned timing for the announcement of data from the ARTEMIS clinical trial for AR101; Aimmune's expectations regarding the sufficiency of its cash resources; 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 expectation 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.

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	March 31, 2019 (Unaudited)	December 31, 2018 (1)
Assets		
Cash and cash equivalents	$ 81,058	$ 107,511
Short-term investments	202,113	196,421
Prepaid expenses and other current assets	8,220	8,687
Total current assets	291,391	312,619
Long-term investments	13,177	—
Property and equipment, net	26,824	26,328
Operating lease assets	12,247	—
Prepaid expenses and other assets	514	608
Total assets	$ 344,153	$ 339,555
Liabilities and Stockholders' Equity		
Current liabilities	$ 38,091	$ 38,012
Long term debt, net of discount	37,268	—
Operating lease liabilities, non-current	11,633	—
Other liabilities	860	2,596
Stockholders' equity	256,301	298,947
Total liabilities and stockholders' equity	$ 344,153	$ 339,555

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Operating Expenses		
Research and development(1)	$ 31,316	$ 33,446
General and administrative(1)	23,712	16,673
Total operating expenses	55,028	50,119
Loss from operations	(55,028)	(50,119)
Interest income, net	791	636
Loss before provision for income taxes	(54,237)	(49,483)
Provision for income taxes	29	17
Net loss	$ (54,266)	$ (49,500)
Net loss per common share, basic and diluted	$ (0.87)	$ (0.92)
Shares used in computing net loss per common share, basic and diluted	62,022	53,578

(1) Includes stock-based compensation expenses of:

	Three Months Ended March 31,	
	2019	**2018**
Research and development	$ 2,743	$ 2,047
General and administrative	5,022	5,560
Total stock-based compensation expenses	$ 7,765	$ 7,607

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