Aimmune Therapeutics Announces Fourth Quarter and Full Year 2018 Financial Results and Provides Recent Operational Highlights

FDA decision on AR101 BLA filing acceptance expected by end of March
Submission of AR101 marketing application in Europe on track for mid-2019
Initiation of AR201 phase 2 trial in egg allergy on track for mid-2019
Company began 2019 with approximately $340 million in cash and investments and potential access to an additional $130 million
Webcast and conference call today at 5:00 p.m. ET

BRISBANE, Calif.--(BUSINESS WIRE)--Feb. 28, 2019-- Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced financial results for the fourth quarter and full year 2018.

“Last year was one of exceptional progress for Aimmune on multiple fronts as we advance AR101 to potentially be the first approved treatment for peanut allergy,” said Jayson Dallas, M.D., President and CEO of Aimmune. “In addition, we are on track to apply for European marketing approval of AR101 and initiate a phase 2 trial of AR201 for egg allergy, both in the middle of the year. We began 2019 in a strong financial position to commercialize AR101 and advance our pipeline programs. Our priority now is ensuring launch preparedness and continuing to collaborate with the allergy community and regulatory authorities to bring AR101 to the children, teens, and families affected by peanut allergy.”

AR101 Highlights

- **Biologics License Application (BLA) for AR101 submitted**. On December 21, 2018, Aimmune submitted a BLA for AR101 to the U.S. Food and Drug Administration (FDA) for the treatment of peanut allergy in children and adolescents ages 4-17 years. Following the reopening of the U.S. government in January 2019, the FDA initiated review of the BLA for AR101. Aimmune expects that the FDA will determine whether the BLA is acceptable for filing by the end of March 2019. Aimmune is currently engaged in discussions with the FDA regarding the review timeline for the BLA for AR101 in consideration of multiple factors, including: the agency’s initial determination that AR101 is exempt from PDUFA; AR101’s Breakthrough Therapy designation; and the apparent lack of precedent for the FDA reviewing a BLA for a PDUFA-exempt product candidate that has Breakthrough Therapy designation. If the Breakthrough Therapy designation for AR101 does not result in an expedited review of the BLA for AR101, the BLA will likely be reviewed under a 12-month target review period applicable to PDUFA-exempt applications, as measured from the January 2019 start date.
- **POSEIDON trial initiated.** In December 2018, Aimmune initiated its phase 3 POSEIDON trial to explore the efficacy and safety of AR101 in young peanut-allergic children, ages 1-3.
- **PALISADE results published in *NEJM*.** In November 2018, the *New England Journal of Medicine* (*NEJM)* published the results of Aimmune’s landmark phase 3 PALISADE trial, the largest and most rigorously conducted oral immunotherapy trial for the treatment of peanut allergy and the only successful phase 3 trial for the treatment of peanut allergy ever conducted.
- **AR101 with adjunctive dupilumab trial initiated.** 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.
- **Data presented at AAAAI.** Aimmunepresented nine abstracts at the American Academy of Allergy, Asthma and Immunology (AAAAI) 2019 Annual Meeting. Notably, new data show that AR101 treatment reduced accidental exposures to peanut requiring medication and increased the amount of peanut tolerated with additional time on the AR101 300 mg daily dose.

AR201 Highlights

- **Phase 2 program on track.** Aimmune’s Investigational New Drug (IND) application for AR201 has been cleared by the FDA and the company expects to begin a phase 2 trial in mid-2019.

Corporate Highlights

- **Strengthened balance sheet.** In November 2018, Nestlé Health Science made an additional $98 million equity investment in Aimmune. In January 2019, Aimmune announced it had entered into a loan agreement with KKR, a leading global investment firm, for up to $170 million to fund AR101 commercialization and pipeline development.
- **Board of Directors expanded.** In November 2018, Aimmune announced the appointment of Brett Haumann, M.B.B.Ch., M.B.A., to its Board of Directors. Dr. Haumann brings extensive biotech and pharmaceutical leadership experience, including more than 20 years of development and discovery work in

allergy and pulmonary medicines.

- **Chief Commercial Officer appointed.** In January 2019, Aimmune named Andrew Oxtoby, a proven pharmaceutical leader, as the company's first Chief Commercial Officer. Mr. Oxtoby joins Aimmune with deep, global experience with successful product launches, commercialization and strategic planning. In this role, Mr. Oxtoby's immediate focus is the potential U.S. launch of AR101.

Upcoming Milestones

1Q 19	Potential acceptance of AR101 BLA for review by the U.S. FDA
1H 19	ARTEMIS data on AR101 available
Mid 19	Initiate phase 2 clinical trial of AR201 in egg allergy
Mid 19	Submit Marketing Authorization Application for AR101 to the European Medicines Agency

Fourth Quarter Financial Results

For the quarter and year ended December 31, 2018, net loss was $57.0 million and $210.8 million, respectively, compared to net loss of $41.2 million and $131.3 million for the comparable periods in 2017.

On a per share basis, net loss for the quarter and year ended December 31, 2018, was $0.95 and $3.67, respectively, compared to net loss per share of $0.81 and $2.61 for the comparable periods in 2017. The weighted average shares outstanding for the quarter and year ended December 31, 2018, was 59.8 million and 57.4 million, respectively, compared to 50.8 million and 50.4 million shares for the comparable periods in 2017.

Research and development expenses for the quarter and year ended December 31, 2018, were $33.0 million and $133.4 million, respectively, compared to $28.7 million and $89.3 million for the comparable periods in 2017. The increase was primarily due to higher costs from the progression of certain AR101 clinical trials and higher contract manufacturing costs to support clinical development and regulatory activities.

General and administrative expenses for the quarter and year ended December 31, 2018, were $25.4 million and $81.9 million, respectively, compared to $13.0 million and $43.9 million for the comparable periods in 2017. 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. Stock-based compensation expense also increased primarily due to the expansion and extension of our long-term commercial supply agreement with Golden Peanut Company and modification of certain executives' stock options resulting from their planned separation.

Cash, cash equivalents, and investments totaled $303.9 million on December 31, 2018, compared to $182.4 million on December 31, 2017. The increase primarily reflects net cash proceeds of $300.0 million resulting from the issuance of our common stock, partially off-set by cash used in operating activities of $169.1 million and cash used for the purchase of plant and equipment of $9.4 million.

Conference Call

In connection with this announcement, Aimmune Therapeutics will host a conference call and webcast today at 5:00 p.m. ET. To access the live call by phone, dial (877) 497-1438 (domestic) or +1 (262) 558-6296 (international) and enter the passcode 4097229. 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 using CODIT™, AR101 for the treatment of peanut allergy, has received the FDA's Breakthrough Therapy Designation for the desensitization of peanut-allergic patients 4-17 years of age. Aimmune's regulatory filing for marketing approval of AR101 in the United States (submitted 4Q18) is based on data from the pivotal Phase 3 PALISADE clinical trial of AR101, which in 4-17 year-old subjects met its primary and key secondary endpoints, and additional ongoing and completed AR101 clinical trials. 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 potential commercial launch of AR101, including the timing of a potential acceptance and 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; Aimmune’s expectations on the planned timing for the announcement of data from the ARTEMIS clinical trial for AR101; Aimmune’s expectations regarding the timing and availability of the full amount of proceeds under its loan agreement with KKR; 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; the satisfaction of closing conditions for each tranche of its loan agreement; 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 September 30, 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 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)

	December 31, 2018 (Unaudited)	December 31, 2017(1)
Assets		
Cash and cash equivalents	$ 107,511	$ 73,487
Short-term investments	196,421	108,943
Prepaid expenses and other current assets	8,687	6,681
Total current assets	312,619	189,111
Property and equipment, net	26,328	17,205
Prepaid expenses and other assets	608	618
Total assets	$ 339,555	$ 206,934
Liabilities and Stockholders’ Equity		
Current liabilities	$ 38,012	$ 26,599
Other liabilities	2,596	2,530
Stockholders’ equity	298,947	177,805
Total liabilities and stockholders’ equity	$ 339,555	$ 206,934

(1)Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Quarter Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Operating Expenses				
Research and development(1)	$33,029	$28,654	$133,420	$89,325
General and administrative(1)	25,404	12,986	81,921	43,949
Total operating expenses	58,433	41,640	215,341	133,274
Loss from operations	(58,433)	(41,640)	(215,341)	(133,274)
Interest income, net	1,417	530	4,650	2,005
Loss before provision for income taxes	(57,016)	(41,110)	(210,691)	(131,269)
(Benefit) Provision for income taxes	(18)	56	61	56
Net loss	$(56,998)	$(41,166)	$(210,752)	$(131,325)
Net loss per share, basic and diluted	$(0.95)	$(0.81)	$(3.67)	$(2.61)
Shares used in computing net loss per basic and diluted share	59,780	50,839	57,403	50,401

(1)Includes employee stock-based compensation expense of:

	Quarter Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Research and development	$2,569	$1,595	$9,945	$5,077
General and administrative	5,500	3,253	22,787	11,642
Total stock-based compensation expense	$8,069	$4,848	$32,732	$16,719

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Source: Aimmune Therapeutics, Inc.

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