Aimmune Therapeutics And KKR Enter Into $170M Loan Agreement To Fund AR101 Commercialization And Pipeline Advancement

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Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced that it has entered into a $170 million loan agreement with an affiliate of KKR, a leading global investment firm.

'The addition of the KKR loan financing to Aimmune's capital resources is expected to fully fund the commercialization of AR101, an investigational biologic oral immunotherapy for the treatment of peanut allergy,' said Eric Bjerkholt, Chief Financial Officer of Aimmune Therapeutics. 'In addition, this financing secures resources to support the continued advancement of our pipeline of additional food allergy treatments, including the Phase 2 trial of AR201 for egg allergy, which is anticipated to commence this year.'

In December 2018, Aimmune submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for AR101 for the treatment of peanut allergy in children and adolescents ages 4-17 years based on data from the landmark Phase 3 PALISADE trial, which met its primary and key secondary endpoints, and from additional ongoing and completed AR101 clinical trials. The FDA has granted Breakthrough Therapy Designation to AR101 for the desensitization of peanut-allergic patients 4-17 years of age.

The loan agreement provides Aimmune with an up to $170 million term loan in three tranches. Forty million dollars was funded at close, with $85 million to follow upon FDA approval of AR101 and satisfaction of other customary borrowing conditions, and $45 million at the company's option in 2020 upon the satisfaction of certain borrowing conditions. The loan can be prepaid at Aimmune's discretion, at any time, subject to prepayment fees. Further information with respect to the term loan is set forth in a Form 8-K filed by Aimmune with the Securities and Exchange Commission on January 4, 2019.

Aimmune reported September 30, 2018, cash, cash equivalents and short-term investments of $255 million. With the $98 million equity investment from Nestlé Health Science announced in November 2018 and the $170 million KKR loan, assuming full borrowings under all tranches, Aimmune's capital resources as of September 30, 2018, would have exceeded $500 million.

For KKR, the investment is part of the firm's Health Care Royalty and Income strategy, which is focused on providing non-dilutive capital to companies for which KKR can help reach scale and achieve strategic objectives.

'Aimmune is leading the way in meeting the critical, growing need to offer treatment to the millions of people affected by food allergies,' said Emily Janvey, M.D., Head of Health Care Royalty and Income strategy at KKR. 'We're proud to help support Aimmune's important work, especially as the company prepares to launch what could be the world's first approved medical treatment for peanut allergy.'

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing oral treatments for life-threatening food allergies. The company's Characterized Oral Desensitization ImmunoTherapy (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™ is AR101. Aimmune intends to submit a regulatory filing for marketing approval of AR101 in Europe during the first half of 2019 based on data from Aimmune's 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 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 the first half of 2019. For more information, please see www.aimmune.com.

About KKR

KKR is a leading global investment firm that manages multiple alternative asset classes, including private equity, energy, infrastructure, real estate and credit, with strategic partners that manage hedge funds.

KKR aims to generate attractive investment returns for its fund investors by following a patient and disciplined investment approach, employing world-class people, and driving growth and value creation with KKR portfolio companies. KKR invests its own capital alongside the capital it manages for fund investors and provides financing solutions and investment opportunities through its capital markets business. References to KKR's investments may include the activities of its sponsored funds. For additional information about KKR & Co. Inc. (NYSE: KKR), please visit KKR's website at www.kkr.com and on Twitter @KKR_Co.

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 timing and availability of the full amount of proceeds under the loan agreement; Aimmune's expectations regarding the sufficiency of its cash resources; Aimmune's expectations regarding the potential benefits of AR101; Aimmune's expectations regarding the potential commercialization of AR101, including the timing of a potential approval of AR101; Aimmune's expectations on the timing of initiating a Phase 2 clinical trial for AR201; Aimmune's expectations on regulatory submissions for marketing approval of AR101 for peanut allergy 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 satisfaction of closing conditions for each subsequent tranche of the loan agreement; 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; 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 that is under clinical investigation, and AR201, a product that Aimmune expects will be under clinical investigation in 2019. Neither AR101 nor AR201 has been approved for marketing by the U.S. Food and Drug Administration (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.

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