Aridis Provides Corporate Update

LOS GATOS, Calif., March 31, 2023 /GlobeNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS) ("Aridis" or the "Company"), a biopharmaceutical company, today announced a corporate update on recent developments.

The Company received written notice from MedImmune Limited ("MedImmune") terminating a certain license covering AR-320, a product candidate currently being evaluated for the prevention of Ventilator Acquired Pneumonia (VAP) in a Phase 3 clinical trial, between the companies ("License Agreement"), dated July 12, 2021 and amended August 9, 2021, due to a license payment matter. Based on the failure of MedImmune to assist in the necessary technology transfer pursuant to Section 3.5.2 of the License Agreement, the Company notified MedImmune on March 24, 2023 that it was in material breach of Section 3.5.2 and requested that the material breach be cured as soon as possible. As a result of this sudden, unexpected termination, Aridis has placed its AR-320-003 Phase 3 clinical study on hold.

"While we seek a remedy to the license dispute, we want to assure our shareholders that we remain steadfastly committed to developing our pipeline products as potential breakthrough therapies to fight antimicrobial resistance," said Aridis' CEO Vu Truong, PhD.

The Company's operating expenses have been significantly lowered with the AR-320-003 trial on hold, and it has reduced its full-time employee headcount by seven and now has 26 full-time employees.

With positive trends in the data from the Company's Phase 3 study of AR-301 in VAP and its Phase 2a study of AR-501 in cystic fibrosis (CF), Aridis remains focused on advancing the continued development of these programs.

"The potential for AR-301 to provide pharmacoeconomic benefits and to fulfill an unmet need in high-risk, vulnerable patient populations is driving interest from possible pharmaceutical partners," added Dr. Truong. "We believe the consistency of clinical efficacy trends and the magnitude of clinical response associated with AR-301 treatment bode well for continued development, and we are moving forward with preparations for the planned second Phase 3 study of AR-301 to build value for our shareholders."

The Company expects to receive feedback from both the FDA and EMA on the second Phase 3 study design for AR-301 by the end of April 2023.

The dosing of the first six CF patients of the highest dose cohort (80mg) in the Company's Phase 2a study of AR-501 is now complete. Safety data from this cohort will be reviewed and discussed with the Cystic Fibrosis Foundation to explore additional potential development collaborations.

Craig Gibbs, Ph.D., officially stepped down from Aridis' board of directors on March 27, 2023, to devote more time and attention to managing Asher Biotherapeutics. Dr. Truong commented, “We are indebted to Dr. Gibb’s long-standing contributions to our board and wish him the very best going forward.” Aridis has initiated a search for a new board member to replace Dr. Gibbs.

About Aridis Pharmaceuticals, Inc.

Aridis Pharmaceuticals, Inc. discovers and develops anti-infectives to be used as add-on treatments to standard-of-care antibiotics. The Company is advancing multiple clinical stage mAbs targeting bacteria that cause life-threatening infections such as ventilator associated pneumonia (VAP) and hospital acquired pneumonia (HAP), in addition to preclinical stage antiviral mAbs. The use of mAbs as anti-infective treatments represents an innovative therapeutic approach that harnesses the human immune system to fight infections and is designed to overcome the deficiencies associated with the current standard of care which is broad spectrum antibiotics. Such deficiencies include, but are not limited to, increasing drug resistance, short duration of efficacy, disruption of the normal flora of the human microbiome and lack of differentiation among current treatments. The mAb portfolio is complemented by a non-antibiotic novel mechanism small molecule anti-infective candidate being developed to treat lung infections in cystic fibrosis patients. The Company’s pipeline is highlighted below:

Aridis' Pipeline

AR-301 (VAP). AR-301 is a fully human IgG1 mAb targeting gram-positive *Staphylococcus aureus* (*S. aureus)* alpha-toxin that has recently completed the first of two planned Phase 3 superiority clinical studies as an adjunctive treatment of *S. aureus* ventilator associated pneumonia (VAP).
AR-320 (VAP). AR-320 is a fully human IgG1 mAb targeting *S. aureus* alpha-toxin that is being evaluated in a Phase 3 clinical study as a preventative treatment of *S. aureus* colonized mechanically ventilated patients who do not yet have VAP.
AR-501 (cystic fibrosis). AR-501 is an inhaled formulation of gallium citrate with broad-spectrum anti-infective activity being developed to treat chronic lung infections in cystic fibrosis (CF) patients. This program is currently in Phase 2a clinical development in CF patients.
AR-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that are directed at multiple protein epitopes on the SARS-CoV-2 virus. It is formulated for delivery via intramuscular injection or inhalation using a nebulizer.
AR-401 (blood stream infections). AR-401 is a fully human mAb preclinical program aimed at treating infections caused by gram-negative *Acinetobacter baumannii*.
AR-101 (HAP). AR-101 is a fully human immunoglobulin M, or IgM, mAb in Phase 2 clinical development targeting *Pseudomonas aeruginosa* (*P. aeruginosa)* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide.
AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb out-licensed preclinical program aimed at neutralizing diverse clinical isolates of respiratory syncytial virus (RSV).

For additional information on Aridis Pharmaceuticals, please visit https://aridispharma.com/.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Aridis' expectations, strategy, plans or intentions. These forward-looking statements are based on Aridis' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the need for additional financing, the timing of regulatory submissions, Aridis' ability to obtain and maintain regulatory approval of its existing product candidates and any other product candidates it may develop, approvals for clinical trials may be delayed or withheld by regulatory agencies, risks relating to the timing and costs of clinical trials, risks associated with obtaining funding from third parties, management and employee operations and execution risks, loss of key personnel, competition, risks related to market acceptance of products, intellectual property risks, risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses, risks associated with the uncertainty of future financial results, Aridis' ability to attract collaborators and partners and risks associated with Aridis' reliance on third party organizations. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, market conditions and the factors described under the caption "Risk Factors" in Aridis' 10-K for the year ended December 31, 2021 and Aridis' other filings made with the Securities and Exchange Commission. Forward-looking statements included herein are made as of the date hereof, and Aridis does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

Contact:

Media Communications:
Matt Sheldon
RedChip Companies Inc.
Matt@redchip.com
1-917-280-7329

Investor Relations
Dave Gentry
RedChip Companies Inc.
ARDS@redchip.com
1-800-733-2447

SOURCE Aridis Pharmaceuticals, Inc.