Aridis Pharmaceuticals

Aridis Pharmaceuticals Reports Phase 2 Clinical Trial Results of AR-105 for the Treatment of Ventilator-Associated Pneumonia Caused by Pseudomonas Aeruginosa

SAN JOSE, Calif., Sept. 3, 2019 /PRNewswire/ -- **Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS)**, a biopharmaceutical company focused on the discovery and development of novel anti-infective therapies to treat life-threatening bacterial infections, today announced results from the Company's first-in-patient Phase 2 clinical trial evaluating AR-105, a fully human IgG1 monoclonal antibody for the treatment of ventilator-associated pneumonia (VAP) caused by gram-negative Pseudomonas aeruginosa *(P. aeruginosa)*. The recently completed study did not meet its primary endpoint of demonstrating superiority in Clinical Cure rates on Day 21 compared to placebo. Furthermore, there was a statistically significant imbalance in all-cause mortality, as well as Serious Adverse Event (SAE) rates between treatment groups that favored placebo. However, no SAE or mortality in the study was deemed to be drug related by the study investigators or the study's Data Monitoring Committee. At this point, the Company will no longer allocate further development resources to AR-105.

"Our team is analyzing the full data set to better understand these top-line results and report the final analysis as soon as possible. We wish to extend our appreciation to the patients, their families, and investigators for their contribution to the study," commented Wolfgang Dummer, M.D., Ph.D., Chief Medical Officer of Aridis Pharmaceuticals.

"I want to underscore our gratitude for efforts of the investigators, patients, and families from which a substantial body of data has been generated that will guide further development of anti-infective immunotherapies," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Moving forward, we remain enthusiastic about and will re-focus on the balance of our robust pipeline including AR-301 and AR-501 which are both in clinical development. Our lead antibody, AR-301, targets gram-positive *S. aureus* alpha-toxin and is currently in Phase 3 global clinical development for the treatment of VAP. This trial is progressing on track, and we look forward to reporting interim data in the first half of 2020 as well as the subsequent top-line data in late 2020."

The AR-301 Phase 3 trial, which was initiated in the first quarter of 2019, is actively enrolling in approximately 240 clinical centers in 20 countries. Participating centers in all countries are following a single stringent clinical protocol and standard of care procedures for critically ill VAP patients. The trial represents the first ever Phase 3 superiority clinical study evaluating immunotherapy with a fully human monoclonal antibody for the treatment of acute pneumonia in the intensive care unit (ICU) setting. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03816956.

AR-301 is a fully human monoclonal IgG1 antibody that was derived from our proprietary MabIgX® platform technology, specifically targeting gram-positive *S. aureus* alpha-toxin, which is a secreted toxin well-known as being central and indispensable to the pathogenesis of this bacteria. It has been shown *in vitro* to protect against alpha-toxin mediated destruction of host cells, thereby potentially preserving the human immune response. AR-301's anti-toxin target and mode of action are different from AR-105's cell surface carbohydrate target and mode of action, and is independent of the antibiotic resistance profile of *S. aureus.* Additional external validation of targeting *S. aureus* alpha-toxin has also been obtained from AstraZeneca's MEDI-4893, another monoclonal antibody against this epitope, which is in development for the prophylaxis of *S. aureus* VAP.

The Company also remains on track with its AR-501 program, an inhaled formulation of gallium citrate being developed as a non-antibiotic anti-infective to treat lung infections in cystic fibrosis patients, with top-line data from its Phase 1/2a clinical trial in healthy subjects and cystic fibrosis patients. The data from the healthy subjects is expected by the end of Q1 2020 and from cystic fibrosis patients in Q2 2021. External validation of successful treatment of cystic fibrosis patients with an intravenous formulation of gallium was reported recently from a Phase 2 clinical study conducted by the University of Washington with an acceptable safety profile and statistically significant improvement in lung function.

Additionally, the Company continues to utilize its proprietary MabIgX® technology platform to rapidly identify rare, potent antibody-producing B-cells from patients to develop new anti-infective monoclonal antibodies.

About AR-105
The development of AR-105, a mAb targeting a cell surface carbohydrate (alginate) on *P. aeruginosa,* was based on animal models of acute pneumonia, sepsis and keratitis which supported its usage as both a therapeutic and prophylactic therapy. Focusing on AR-105's therapeutic use, a Phase 1 dose-ranging, clinical trial was conducted involving 16 healthy adult volunteers who received up to a 20 mg/kg IV dose of this agent. In this study, AR-105 was shown to be safe and well tolerated and exhibited a plasma half-life of approximately 21 days. This trial informed the choice of both the dose (20 mg/kg) and schedule (one IV injection) for the Phase 2- trial.

The Phase 2 trial (ClinicalTrials.gov Identifier: NCT03027609), which was initiated in the second quarter of 2017, was a randomized, double blinded, placebo controlled, superiority study which treated 158 VAP patients in 53 clinical sites from 13 countries across the U.S., Europe and Asia. Patient enrollment was based on admittance to an intensive care unit for pneumonia caused by *P. aeruginosa* bacteria as determined using a rapid diagnostic and/or culture test. Such VAP patients were randomized in a 1:1 fashion to receive either standard-of-care antibiotic therapy with placebo (placebo arm) or standard-of-care antibiotic therapy in addition to AR-105 (experimental arm). The treatment regimen was a single intravenous infusion (IV) of either AR-105 at a dose of 20 mg/kg or placebo. The primary endpoint of this trial was clinical cure of pneumonia at Day 21 post study drug treatment, as determined by the principal investigator. The trial was designed to demonstrate statistical superiority of AR-105 over standard-of-care. Secondary endpoints of the trial included clinical cure of pneumonia at Day 28, Day 14, or Day 7, all-cause mortality, and several health economics parameters.

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 utilizing its proprietary MabIgX® technology platform to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection to produce mAbs. These mAbs are already of human origin and functionally optimized for high potency by the donor's immune system; hence, they do not require genetic engineering or further optimization to achieve full functionality. MabIgX® also allows for the selection of any antibody isotype depending on the optimal effector function required for treating the target infection. By bypassing the humanization and binding sequence optimization steps, and the entire process of generation of genetically engineered antibody producing cell lines, MabIgX® enables high gross-margins and expedited progression to clinical development.

The Company has generated multiple clinical stage mAbs targeting bacteria that cause life-threatening infections such as VAP and HAP. 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 immunoglobulin 1, or IgG1, mAb currently in Phase 3 clinical development targeting gram-positive *S. aureus* alpha-toxin in VAP patients.

AR-101 (HAP). AR-101 is a fully human immunoglobulin M, or IgM, mAb targeting *P. aeruginosa* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide.

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 patients. This program is currently in a Phase 1/2a clinical study in healthy volunteers and CF patients.

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-201 (RSV infection). AR-201 is a fully human IgG1 mAb 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 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 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, 2018 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:

Investor Relations
Jason Wong
Blueprint Life Science Group
jwong@bplifescience.com
(415) 375-3340 Ext. 4

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