Aridis Pharmaceuticals

AR-501 (Cystic Fibrosis) Enrolls First Subject in Phase 1/2a Clinical Trial for Treatment of Chronic Lung Infections in Cystic Fibrosis Patients

- Two-Part Randomized, Double-Blinded Placebo Controlled Clinical Study in Healthy Subjects Followed by Cystic Fibrosis Patients Enrolls First Adult Human Volunteer
- Study Being Performed in Collaboration with the Cystic Fibrosis Foundation

SAN JOSE, Calif., Dec. 12, 2018 /PRNewswire/ -- **Aridis Pharmaceuticals** (NASDAQ: ARDS) announced today that the first subject has been enrolled in a Phase 1/2a clinical study evaluating the investigational candidate AR-501 for treatment of chronic bacterial lung infections in patients with cystic fibrosis (CF).

"We are pleased to initiate this exciting program with the first subject enrolled**,"** said Wolfgang Dummer, M.D., Ph.D., Chief Medical Officer of Aridis. "Through this trial, we anticipate safety, pharmacokinetic, and exploratory efficacy data that will enable us to further explore the potential of AR-501 in the treatment of these life-threatening bacterial infections in cystic fibrosis patients."

The AR-501 study is a randomized, double-blinded, placebo controlled single and multiple dose-ascending Phase 1/2a clinical trial investigating the safety and pharmacokinetics of inhaled AR-501 (gallium citrate) in healthy volunteers and cystic fibrosis patients with chronic bacterial lung infections. The study will accrue 48 healthy adult volunteers and 48 cystic fibrosis patients from approximately 15 sites in the U.S. Phase 1 data are anticipated during the fourth quarter of 2019 and Phase 2a data are anticipated for the fourth quarter of 2020. The lead investigator for the study is Dr. Noah Lechtzin, Director of the Adult Cystic Fibrosis Program and Associate Professor of Medicine at Johns Hopkins University.

"The recent safety and efficacy demonstration of intravenous gallium from a Phase 2 clinical study in CF patients gives us optimism of the prospect inhaled delivery of gallium (AR-501), which is a more direct, local route of delivery to the site of infection in the lungs and less systemic exposure," said Dr. Dummer.

The Phase 1/2a trial is part of a collaboration with the Cystic Fibrosis Foundation, which has committed up to $7.5 million in funding through Phase 1/2a.

About AR-501

AR-501 is an inhaled formulation of gallium citrate that is being developed to treat chronic lung infections in cystic fibrosis patients. Its anti-infective mechanism of action is different from antibiotics. AR-501 acts as an iron analog and is believed to disrupt multiple iron dependent pathways in microbes, leading to growth inhibition. AR-501 has antimicrobial activities against a number of gram-negative and gram-positive bacteria, including antibiotic resistant strains. Preclinical studies have shown that mice infected with *P. aeruginosa* bacteria can be rescued from mortality with a single inhalation exposure of aerosolized AR-501. This drug candidate is being developed as a once-per-week dosing regimen that is self-administered using a hand-held nebulizer device. The planned Phase 1/2a clinical study involves single and multiple ascending dose cohorts that are drawn from the healthy adult volunteers as well as cystic fibrosis adult patients. For additional information about this study, please visit https://clinicaltrials.gov/ct2/show/NCT03669614?term=ar-501&rank=1. For additional information on the outcome of the Phase 2 clinical study intravenous gallium in CF patients, please visit https://clinicaltrials.gov/ct2/show/NCT02354859?term=gallium+nitrate&rank=5. Aridis has exclusive global commercial rights to AR-501.

About Cystic Fibrosis with *Pseudomonas aeruginosa* Infection

There are more than 70,000 patients with cystic fibrosis worldwide, and 80 percent of these patients present with chronic polymicrobial infections, particularly *P. aeruginosa* infection. Aridis believes the medical need and market potential for an anti-infective therapeutic that can be provided to cystic fibrosis patients chronically is substantial. The current market for inhaled antimicrobials for cystic fibrosis, based on recent combined sales figures for TOBI (tobramycin) and Cayston (aztreonam), is approximately $600 million worldwide. Existing therapies often lead to a temporary improvement in bacterial load, but most cystic fibrosis patients ultimately succumb to respiratory failure due to *P. aeruginosa* infection.

About Aridis Pharmaceuticals, Inc.

Aridis is a late-stage biopharmaceutical company focused on discovering and developing innovative anti-infectives, such as targeted immunotherapies using fully human monoclonal antibodies (mAbs) to treat life-threatening infections. The use of mAbs represents an innovative treatment approach that harnesses the

human immune system to fight infections and is designed to overcome the deficiencies associated with the current standard of care, broad spectrum antibiotics.

The most common deficiencies of antibiotics, include: propensity for drug resistance, short duration of activity, and perturbation of the human microbiome, while offering marginal differentiation among one another in safety and efficacy.

Aridis' Pipeline

AR-301 (ventilator associated pneumonia). AR-301 is a fully human immunoglobulin 1, or IgG1, mAb currently in Phase 3 clinical development targeting gram-positive *S. aureus* alphatoxin in ventilator-associated pneumonia, or VAP, patients.

AR-105 (ventilator associated pneumonia). AR-105 is a fully human IgG1 mAb targeting gram-negative *P. aeruginosa* alginate in VAP patients. AR-105 is currently being evaluated in a global Phase 2 clinical study.

AR-101 (hospital acquired pneumonia). 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. A Phase 2/3 clinical study is expected to initiate in 2H2019.

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 cleared to initiate a Phase 1/2a clinical study in 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 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-Q for the quarter ended June 30, 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.

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