Aridis Pharmaceuticals

Aridis Reports AR-501 Clinical Data: Positive Safety Data in Healthy Subjects of a Phase 1/2a Clinical Trial

- Phase 1 portion of the Phase 1/2a trial, 48 healthy volunteers were treated with either single or multiple weekly dose regimens
- No serious adverse events and well tolerated
- AR-501 Phase 2a received recommendations to proceed from the Data Safety Monitoring Board (DSMB) from the CF Foundation and study's Safety Monitoring Committee (SMC)

SAN JOSE, Calif., June 22, 2020 /PRNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of novel anti-infective therapies to treat life-threatening infections, announced today positive results from the Phase 1 portion of its Phase 1/2a clinical trial of AR-501, an inhaled formulation of gallium citrate being developed for the treatment of chronic lung infections in patients with cystic fibrosis (CF). The Phase 1/2a clinical trial, which is being funded by the Cystic Fibrosis Foundation, is a randomized, double blinded, placebo-controlled study evaluating the safety and pharmacokinetics in healthy volunteers and *Pseudomonas aeruginosa* infected CF patients. AR-501 is being developed as a once-per-week dosing regimen that is self-administered using a hand-held nebulizer device.

Key findings:

- AR-501 aerosols were well tolerated
- No serious adverse events (SAEs), no Grade 3 or Grade 4 adverse events (AEs) reported over the 28 day study period for the single ascending dose cohort, or 56 day study period for the multiple ascending dose cohort
- All AEs were Grade 1 or Grade 2 in severity that resolved
- Most common AEs were respiratory and were balanced between AR-501 and placebo recipients
- Transient incremental changes in airflow as measured by spirometry were observed in both AR-501 and placebo recipients that were not dose related
- The SMC and DSMB support all doses to proceed to the Phase 2a portion of the Phase 1/2a trial in adult subjects with CF

"We know that a recent Phase 2 clinical study showed that intravenous, 5-day continuous infusion of gallium is safe and effective in improving lung functions of cystic fibrosis patients. Our current data is extremely exciting as it shows that gallium is also well tolerated when delivered directly to the lungs in a more convenient, once-per-week, inhaled form that is likely capable of achieving substantially higher lung exposure than the intravenous route," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "We look forward to advancing to the Phase 2a stage of the study evaluating adult cystic fibrosis patients, with results expected in 2H 2021."

About the Phase 1/2a Clinical Trial
The study was designed to enroll 48 healthy adult volunteers (Phase 1) and 48 cystic fibrosis patients (Phase 2a) from approximately 18 sites in the U.S. In the now-completed Phase 1 arm, 48 healthy adults were randomized and treated in 6 cohorts (of 8 subjects each) to receive either a single ascending dose (SAD, Cohorts 1, 2, and 3 [N=24]) or weekly multiple ascending doses (MAD, Cohorts 4, 5, and 6 [N=24]) of active drug at 6.4 mg gallium (Ga^{+3}), 20 mg Ga^{+3} and 40 mg Ga^{+3} or placebo. Phase 1 participants were randomized within each cohort in a 3:1 ratio of active drug to placebo. Subjects were followed for 28 days after study dose for safety and PK of inhaled AR-501 in HV subjects. AR-501 or placebo was delivered by a nebulizer device. For additional information about this study, please visit https://clinicaltrials.gov/ct2/show/NCT03669614?term=ar-501&rank=1.

About AR-501 and Cystic Fibrosis
AR-501 is an inhaled formulation of gallium citrate that is being developed to treat chronic lung infections in cystic fibrosis patients. It is a non-antibiotic, broad acting antimicrobial with a mechanism of action involving interference with iron and disruption of microbial iron-dependent metabolic pathways distinct from current 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.

Cystic fibrosis patients often suffer from severe, persistent secondary bacterial lung infections due to their underlying lung disease which results in an immune-compromised state. Preclinical efficacy and safety data have demonstrated that AR-501 works synergistically with multiple antibiotics, is effective against antibiotic

resistant strains, and has a low intrinsic resistance profile. AR-501 is being developed as a self-administered, inhaled weekly treatment. Separately, an intravenous formulation of gallium nitrate citrate has been evaluated in Phase 1 and Phase 2 clinical studies as a single, 5-day infusion in moderate and severe cystic fibrosis patients by researchers at the University of Washington (Seattle, WA). Both clinical studies of IV gallium demonstrated safety and efficacy as measured by improvement in lung function. AR-501 received Orphan Drug, Fast-Track, and QIDP (Qualified Infectious Diseases Product) designations for the treatment of lung infections in patients with CF by the US FDA. The European Medicines Agency (EMA) also awarded AR-501 with Orphan Drug designation.

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 /\PEX™ and MabIgX® technology platforms to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection, and to rapidly manufacture mAbs for therapeutic treatment of critical infections. 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.

The Company has generated multiple clinical stage mAbs targeting bacteria that cause life-threatening infections such as ventilator associated pneumonia (VAP) and 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 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 in Phase 2 clinical development 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-701 (COVID-19). AR-701 is a fully human mAb cocktail discovered from convalescent COVID-19 patients that are directed at multiple envelope proteins on SARS-CoV-2.

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 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, 2019 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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