Aridis Pharmaceuticals

Aridis Announces the Closing of Patient Enrollment in the AR-301 Global Phase 3 Superiority Study

- ***On track to complete data compilation and analyses, with top-line data expected to be announced in December '22***

LOS GATOS, Calif., Oct. 4, 2022 /PRNewswire/ -- **Aridis Pharmaceuticals, Inc. (NASDAQ: ARDS)** announced today that patient enrollment is closed in the AR-301 Phase 3 clinical study. The Company is on track to complete database lock, data analyses, and expects to disclose top-line data in December 2022. The AR-301-002 Phase 3 'ASAP-1' study compares the superiority of adjunctive use of the investigational, targeted immunotherapy candidate AR-301 with standard of care (SOC) antibiotics versus SOC antibiotics alone, for the treatment of ventilator associated pneumonia (VAP) caused by Gram-positive bacteria *Staphylococcus aureus* (*S. aureus*). Patients enrolled will complete their treatment and 28-day follow-up per study protocol.

Safety and efficacy of the fully human monoclonal antibody AR-301 (20 mg/kg infusion given once) are being evaluated using a randomized, double-blinded, placebo-controlled, superiority clinical trial design. The study was initiated as a globally harmonized Phase 3 study after the design and primary endpoint of clinical cure of pneumonia were reviewed by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). This global study involved 153 clinical sites in 20 countries across U.S., Latin and South Americas, Europe, and Asia. ASAP-1 is the first ever Phase 3 superiority clinical study evaluating immunotherapy with a human monoclonal antibody to treat acute pneumonia.

"Following the protracted COVID-19 pandemic that has slowed the pace of patient enrollment in clinical trials across the world, we are pleased to reach this key milestone for the study. We are working diligently to gather data from the clinical centers and report top-line results of this landmark Phase 3 study," said Aridis' Chief Medical Officer Hasan Jafri, MD.

In the study, all patients received SOC antibiotics in combination with either AR-301 immunotherapy or placebo by intravenous infusion following the diagnosis of severe pneumonia and confirmation of S. aureus in the patient's lung fluid, using either the classical microbiology test and/or a rapid diagnostic test. The primary endpoint of clinical cure of pneumonia is a composite endpoint which comprises three objectively measured outcomes that must be met for declaration of treatment success, namely 1) survival, 2) removal of mechanical ventilation, and 3) resolution of signs and symptoms of pneumonia. The ongoing Phase 3 study remains blinded. The independent Data Safety Monitoring Committee, which has access to unblinded data, has not expressed any safety concerns. ASAP-1 is the first of two Phase 3 studies required for licensure. Details of the study can be reviewed on www.clinicaltrials.gov website using Identifier NCT03816956.

About AR-301

AR-301 is a fully human IgG1 monoclonal antibody that specifically targets *S. aureus* alpha-toxin, an important virulence factor that is secreted by both methicillin-resistant *S. aureus* (MRSA) and methicillin-susceptible *S. aureus* (MSSA). We believe that AR-301 protects against alpha-toxin mediated destruction of host cells, preserving the human immune cells. AR-301's mode of action is independent of the antibiotic resistance profile of *S. aureus* and it is active against infections caused by both MRSA and MSSA.

About Ventilator Associated Pneumonia (VAP) with *S. aureus* Bacterial Infection

VAP poses serious challenges in the hospital setting, as standard of care antibiotics are becoming inadequate in treating infected patients. There are approximately 251,600 cases of hospital acquired pneumonia reported in the U.S. annually caused by *S. aureus* (Decision Resources Group 2016 data base). These patients are typically at high risk of mortality, which is compounded by other life threatening co-morbidities and rise in antibiotic resistance. Epidemiology studies estimate that the probability of death attributed to *S. aureus* ranges from 29% to 55%. In addition, pneumonia infections can prolong patient stays in ICUs (intensive care units) and the use of mechanical ventilation, creating a major economic burden on patients, hospital systems and payors. For example, ICU cost of care for a ventilated pneumonia patient is approximately $10,000 per day, and the duration of ICU stay is typically twice that of a non-infected ICU patient (Infection Control and Hospital Epidemiology. 2010, vol. 31, pp. 509 515).

About Aridis Pharmaceuticals, Inc.

Aridis Pharmaceuticals, Inc. discovers and develops novel anti-infective therapies to treat life-threatening infections, including anti-infectives to be used as add-on treatments to standard-of-care antibiotics. The

Company is utilizing its proprietary ΛPEX™ 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 monoclonal antibodies (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 typically do not require genetic engineering or further optimization to achieve full functionality.

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 and is being evaluated in a global Phase 3 superiority clinical study 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
Dave@redchip.com
1-800-733-2447

SOURCE Aridis Pharmaceuticals, Inc.
