Aridis Pharmaceuticals

Aridis Pharmaceuticals Enrolls Its First COVID-19 Patient in Ongoing Phase 3 AR-301 Clinical Trial in Ventilator Associated Pneumonia (VAP)

SAN JOSE, Calif., May 4, 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 bacterial infections, announced today the enrollment of its first COVID-19 patient in the Company's ongoing Phase 3 clinical trial of AR-301, a monoclonal antibody against *S. aureus* induced pneumonia in patients who were already on mechanical ventilators.

COVID-19 patients on prolonged mechanical ventilation in the intensive care unit (ICU) are prone to secondary infections (also called 'superinfections') by opportunistic pathogens such as bacteria. Superinfection is a reported complication in COVID-19 patients, which exacerbates morbidity and rate of mortality. The Company's ongoing AR-301 Phase 3 study allows for the enrollment of patients with baseline characteristics which are inclusive of certain COVID-19 patients. "While AR-301 does not treat the virus that causes COVID-19 disease, it can potentially mitigate secondary *S. aureus* bacterial pneumonia, which represents a serious coronavirus complication and a cause of death in such patients," said Vu Truong, Chief Executive Officer.

The AR-301 Phase 3 clinical study was initiated in the first quarter of 2019 and is expected to enroll 240 patients at approximately 160 clinical centers in 22 countries. The trial represents the first ever Phase 3 superiority clinical study evaluating immunotherapy with a fully human monoclonal antibody to treat acute *S. aureus* bacterial pneumonia in mechanically ventilated ICU patients. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03816956.

About Superinfections in COVID-19 Patients
Respiratory viral infections such as influenza, SARS, and MERS are commonly associated with secondary infections by opportunistic pathogens such as bacteria and fungus. While there is currently limited data regarding superinfections/coinfections in COVID-19 pneumonia, morbidity and mortality in COVID-19 disease is thought in part due to secondary infections. Secondary infections occur in approximately 10% to 30% of cases in hospitalized, severely ill COVID-19 patients, with much greater frequency in the ICU setting. COVID-19 patients in the ICU are on mechanical ventilation for a median of 17 days, compared to 5-10 days without COVID-19 disease. Prolonged intubation time is associated with higher risk of hospital-acquired infection by multidrug-resistant bacterial pathogens. Even though the ongoing AR-301 Phase 3 study is not powered for statistical significance in the COVID-19 patient population, the results from the COVID-19 subpopulation could provide preliminary data on the impact of AR-301 on secondary *S. aureus* pneumonia complication in COVID-19 patients.

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 APEX™ and MabIgX® technology platforms to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection, and to 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 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, 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; 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, 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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