Aridis Pharmaceuticals

Aridis' Pan-Coronavirus, Inhaled Monoclonal Antibody Cocktail AR-701 Is Protective in Non-Human Primates

AR-701 is effective in vitro against SARS-CoV-2 Omicron subvariants, including BA.4 and BA.5

LOS GATOS, Calif., Aug. 10, 2022 /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 that inhaled treatment of its fully human monoclonal antibody cocktail AR-701 resulted in no detectable SARS-CoV-2 virus in the lungs of infected rhesus macaques, and protected their lungs from disease. AR-701 was effective in the non-human primates when used either as a prophylactic or therapeutic treatment regimen.

- Therapeutic administration of inhaled AR-701 substantially reduced and continued to suppress the viral load in the nasal sinus and oropharynx (upper respiratory tract region) for the entire 5-day testing period.
- Additional lab research also indicates both mAbs in the AR-701 cocktail are effective against the SARS-CoV-2 Omicron BA.1, BA.2, BA.4, BA.5 subvariants *in vitro*.

This non-human primate research was conducted through a collective effort involving researchers at the Oregon National Primate Research Center (ONPRC) at Oregon Health & Science University (OHSU), the University of California at Davis, Vanderbilt University, the University of California at Irvine, and Aridis, with a grant supplement to OHSU from the National Institutes of Health's Office of Research Infrastructure Programs in the Office of the Director (OD, PHS grant P51 OD011092). Preliminary study results were recently presented at the Immunotherapy for Infectious Diseases Conference 2022 in Pavia, Italy. Additional data are being analyzed and will be submitted to a peer-reviewed scientific journal for publication.

"An efficacy demonstration in non-human primates has been a key milestone and a correlate for clinical success in human trials. The observed strong prophylactic and therapeutic efficacy bodes well for AR-701 and is an important step forward," commented Vu Truong, Ph.D., CEO of Aridis Pharmaceuticals. The proprietary inhaled formulation is designed to deliver the mAbs directly to the site where the SARS-CoV-2 virus initially infects, amplifies, and is transmitted from the infected individual to others. "Given the challenges in maintaining high vaccination coverage and a protracted COVID-19 pandemic, there is a greater need to develop accessible, long-acting therapeutic treatments, especially treatments that can also effectively block person-to-person viral transmission. These data demonstrate that the inhaled, self-administered dosage form of half-life extended AR-701 is on track to meet this product profile," said Truong.

About AR-701

AR-701 is a cocktail of two fully human immunoglobulin G1 (IgG1) mAbs discovered from screening the antibody secreting B-cells of convalescent SARS-CoV-2 infected (COVID-19) patients. Each mAb of the AR-701 cocktail neutralizes coronaviruses using a distinct mechanism of action, namely inhibition of viral fusion and entry into human cells (AR-703) or blockage of viral binding to the human 'ACE2' receptor (AR-720). The activity of the two mAbs complement and enhance each other in a synergistic fashion, creating a potent first-in-class cocktail. AR-720 binds to the 'receptor binding domain' of the spike protein of SARS-CoV-2, while AR-703 binds to the 'S2' stalk region of spike proteins from betacoronaviruses, including the SARS-CoV-2 variants (Beta, Gamma, Delta, Epsilon, and Omicron). Both mAbs bind to the Omicron subvariants, BA.1, BA.2, BA.4, and BA.5 with comparable affinity compared to the original Wuhan strain. All authentic live SARS-CoV-2 beta, gamma, delta, epsilon, and Omicron variants, SARS, and MERS tested were neutralized by both mAbs of AR-701 cocktail *in vitro*. Multiple animal challenge models widely used to evaluate COVID-19 treatments support the broad efficacy of AR-701 against the original Wuhan wildtype strain, the Delta variant, the Omicron variant, and the severe acute respiratory syndrome virus (SARS). The AR-701 mAbs are engineered to be active for 6-12 months in the blood. AR-701 is being developed as a long-acting intramuscular as well as a self-administered inhaled formulation for the treatment of COVID-19 patients who are not yet hospitalized. Aridis Pharmaceuticals recently received a grant from the Bill and Melinda Gates Foundation to evaluate the prevention of influenza and SARS-CoV2 viral transmission using inhaled delivery of monoclonal antibodies.

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 antibody (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 technically 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 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 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.

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