Aridis Pharmaceuticals

Aridis' Pan-Coronavirus Monoclonal Antibody Cocktail AR-701 Is Protective in COVID-19 Omicron Infected Animals

Preventative treatment of animals infected with the Omicron variant with either mAb alone or the combination of the two mAbs comprising the AR-701 cocktail conferred complete protection

LOS GATOS, Calif., Feb. 17, 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 both of its fully human monoclonal antibodies (mAbs) in the AR-701 cocktail neutralized the SARS-CoV-2 Omicron variant. Moreover, both mAbs conferred complete protection against Omicron infected animals when given either parenterally or by intranasal administration.

- Both mAbs in the AR-701 cocktail, i.e., AR-720 and AR-703, neutralized all authentic SARS-CoV-2 beta, gamma, delta, epsilon, and Omicron variants *in vitro*
- Both mAbs of the AR-701 cocktail, when used either individually or in combination, conferred complete eradication of virus from Omicron infected mice and protection against disease pathology.

Aridis Pharmaceuticals has recently received a $1.9 million (USD) grant from the Bill and Melinda Gates Foundation to evaluate the prevention of influenza and SARS-CoV-2 (COVID-19) viral transmission using inhaled delivery of monoclonal antibodies.

"We believe these exciting animal efficacy results are the first of any COVID antibody program to show this level of broad reactivity and efficacy, including in Omicron infected models. Given large scale clinical data from others which showed mAbs are effective as a COVID-19 preventative treatment, we think that AR-701 is well positioned for pan-coronavirus prophylaxis" commented Vu Truong, Ph.D., CEO of Aridis Pharmaceuticals. "In addition to being broadly reactive against all COVID-19 variants, we have previously shown AR-701's effectiveness against SARS, MERS, and seasonal influenza viruses, and importantly, it is engineered for long-acting effectiveness, potentially lasting a year or more when used in humans," continued Dr. Truong. "AR-701 is just one of several exciting programs in our diverse pipeline, which includes two Phase 3 programs in bacterial pneumonia and a Phase 2 program in cystic fibrosis. We look forward to sharing further updates as we continue to move these programs forward."

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-703 binds to the 'S2' stalk region of spike proteins from betacoronaviruses, including the SARS-CoV-2 variants (beta, gamma, delta, epsilon), and binds to the Omicron variant with no loss in affinity compared to the original Wuhan strain. 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, 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. AR-701 mAbs were discovered through a collaboration with researchers at the University of Alabama in Birmingham and Texas Biomedical Research Institute (San Antonio, TX).

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 developed as a preventative treatment of *S. aureus* colonized mechanically ventilated patients who do not yet have VAP. Phase 3 is expected to be initiated in 2Q22.

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-701 replaces AR-712 as the company's leading COVID mAb candidate.

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, 2020 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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