Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces a Pan-Coronavirus Monoclonal Antibody Cocktail That Retains Effectiveness Against the Omicron variant, other COVID-19 Variants, SARS, MERS, and the Common Cold Human Coronaviruses

AR-701 cocktail binds to the Omicron variant with similar effectiveness as to the original Wuhan strain

Viral neutralization and animal infection models support broad prophylaxis and therapeutic efficacy of AR-701 against SARS-CoV-2 and SARS

LOS GATOS, Calif., Dec. 21, 2021 /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 its fully human monoclonal antibody (mAb) cocktail AR-701 is broadly reactive against the Omicron and other COVID-19 (SARS-CoV-2) variants, SARS (Severe Acute Respiratory Syndrome), MERS (Middle East Respiratory Syndrome Coronavirus), and seasonal ('common cold') human coronaviruses.

- AR-703, one of the components of the AR-701 cocktail, binds to the 'S2' stalk region of coronavirus spike proteins that is responsible for viral fusion and entry into host cells, and binds to the Omicron variant with no loss in affinity as compared to the original Wuhan strain.
- In vitro neutralization studies using live coronaviruses showed that AR-701 achieved broad, potent neutralization against all SARS-CoV-2 variants tested, as well as SARS, MERS, and the seasonal 'common cold' betacoronaviruses.
- In vivo data with multiple animal challenge models that are widely used to evaluate COVID-19 treatments support AR-701's broad efficacy.
- AR-701 is engineered to be long-acting, and is expected to provide relevant drug levels for up to 1 year from prophylactic or therapeutic treatment.

"Omicron has rendered current COVID-19 vaccines and monoclonal antibodies substantially less effective, and likely future COVID 19 variants will arise that continue this trend" said Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "AR-701 is the result of our successful search for a mAb therapy that is directed against a conserved region of the virus that would be less vulnerable to mutations and new variants such as Omicron. Our laboratory data suggest that AR-701 has the potential to be a future-proof COVID-19 therapy that can protect against SARS-CoV-2, SARS, or MERS pandemics," continued Dr. Truong. "To our knowledge AR-701 is the only COVID-19 therapy that targets two distinct viral mechanisms of action, making it much harder for the virus to generate resistance, and exhibits an unmatched combination of broad reactivity and high efficacy," continued Dr. 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. AR-701 consists of AR-703 and AR-720 mAbs, each neutralizes coronaviruses using distinct mechanisms of action, namely inhibition of viral fusion and entry into human cells (AR-703) and blockage of viral binding to the human 'ACE2' receptor (AR-720). 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-CoV2 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 AR-701's broad efficacy, including:

- AR-701 mAbs administered parenterally, either individually or in combination with one another, eradicated SARS-CoV-2 (Wuhan strain) from the lungs of infected mice.
- Hamsters infected with the SARS-CoV-2 (Delta variant) and later treated once with inhaled AR-701 mAbs, either individually or in combination, were protected from disease and weight loss.
- Mice infected with the Severe Acute Respiratory Syndrome virus (SARS) were also protected from disease and weight loss with a single inhaled dose of AR-701.

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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