Aridis Pharmaceuticals

Aridis Pharmaceuticals Provides Multiple Program Updates Including the Addition of a Second Inhaled Antibody to Neutralize Newly Emerging COVID-19 Mutated Variants

National Institute of Allergy and Infectious Disease (NIAID) and the Coronavirus Immunotherapy Consortium (CoVIC) are providing preclinical services support to accelerate development

Phase 1/2/3 clinical trial of the inhaled COVID antibody cocktail on track for 2H 2021 initiation

LOS GATOS, Calif., Feb. 23, 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 it has augmented its inhaled AR-711 monoclonal antibody (mAb) to COVID-19 with a second mAb (AR-713) that is designed to neutralize newly emerging COVID-19 mutated variants including those from South Africa, Brazil and Japan. Together, the enhanced dual antibody cocktail will be delivered as an inhaled treatment and is expected to provide broad coverage of all known high-risk strains. In addition, Aridis is pleased to announce preclinical development services support from NIAID. The preclinical development services support is also provided by the Coronavirus Immunotherapy Consortium (CoVIC). Aridis is on track to initiate the program's Phase 1/2/3 clinical trial in 2H 2021.

AR-711 is being developed as a self-administered, at-home inhaled treatment for COVID-19 patients who are not yet hospitalized. The Company's vision is that if highly effective immunotherapies such as mAbs could be formulated as inhaled therapy, then COVID-19 patients could be treated much earlier in the course of their disease within their own homes. This could offer convenience to patients and reduce pressure on medical infrastructure, including outpatient infusion centers and hospitals. As the pandemic evolves, new mutant and more contagious strains of the SARS-CoV-2 virus have emerged, rendering most available vaccines and monoclonal antibodies less effective. In response, the Company is now adding a second mAb AR-713, which has been shown to completely neutralize *in vitro* the 'E484K' mutation containing SARS-CoV-2 variant, associated with the Brazilian and Japanese variants (P.1) and the South African variant (B.1.351). This enhanced cocktail is designed to neutralize these variants as well as the original strain, the D614G strain, and the UK strain (B.1.1.7), providing broad coverage of all currently known high-risk strains.

"As the COVID-19 pandemic spreads globally, the virus continues to mutate into variants which render the majority of the available vaccines and mAbs less effective," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Scientists at Aridis continue to collaborate with multiple global research organizations in their ongoing search for the best agents to target this rapidly-changing virus. We are committed to being nimble and adjust our treatment, as needed, in order to keep pace with the virus as it continues to evolve. The addition of AR-713 follows this strategy of rapid responsiveness."

"Even at peak COVID-19 vaccination coverage, it is expected that up to a third of the world's population will remain unvaccinated and at risk of contracting COVID-19, thus requiring treatment intervention. This is exactly where treatment modalities such as our inhaled COVID-19 mAb cocktail could fill the gap, i.e. by neutralizing the circulating and variant viral strains allowing infected individuals to be treated earlier and recover at home," continued Truong. "We are pleased to deliver a second mAb to provide broad coverage including the newly emerging COVID-19 strains. We are also thankful to our collaborators at NIAID/CoVIC whose lab work is helping us complete our FDA and EMA dossiers for an expeditious start of the Phase 1/2/3 clinical trials."

The Company remains on track to finalize the Phase 1/2/3 design for this program and obtain concurrence from the FDA and EMA in 1H 2021 such that patient enrollment can be initiated in 2H 2021.

About AR-711 and AR-713

AR-711 and AR-713 are fully human immunoglobulin G1 (IgG1) mAbs discovered from screening the antibody secreting B-cells of convalescent SARS-CoV-2 virus infected (COVID-19) patients. These mAbs target the SARS-CoV-2 virus' receptor-binding domain (RBD) region of the spike protein at a distinct, unique site. They are also engineered to be active for 6-12 months in the blood and formulated for effective delivery from commercially available nebulizers. Due to its direct delivery to the lungs by inhaled administration, AR-711 and AR-713 may facilitate more rapid, broader treatment coverage, and at a substantially lower dose as compared to parenteral administration. AR-711 exhibits high affinity for SARS-CoV-2 spike protein, approximately 10-fold higher than other mAb candidates currently in late stage clinical testing, and neutralizes the original SARS-CoV-2 strain, the D614G strain, and the UK strain (B.1.1.7). AR-711 was previously shown to be effective in prophylactic as well as therapeutic treatment modes in a SARS-CoV-2 viral challenge pre-clinical study. AR-713 extends the binding and neutralization of SARS-CoV-2 strains to include the 'E484K' mutation related strains, which include the Brazilian and Japanese variants (P.1) and the South African variant (B.1.351). Both AR-711 and AR-713 were originally discovered through a collaboration with the University of Alabama (Birmingham) and

the Texas Biomedical Research Institute. Collectively, the cocktail of AR-711 and AR-713 are referred to as AR-712.

About NIAID and CoVIC Consortium
NIAID (National Institute of Allergy and Infectious Diseases) is one of the 27 institutes and centers that make up the National Institutes of Health (NIH), an agency of the United States Department of Health and Human Services. CoVIC is a global partnership created to accelerate discovery, optimization, and delivery of antibody-based therapeutics against SARS-CoV-2. It is an academic-industry and non-profit research collaboration that brings together scientists from around the world to study and assess which antibodies are most effective against the coronavirus SARS-CoV-2, and to streamline and accelerate the research pipeline for antibody-based therapeutics needed against SARS-CoV-2. The funders of CoVIC include the Bill & Melinda Gates Foundation, the Wellcome Trust, NIAID, and MasterCard. The company's receiving of the preclinical services support from NIAID and CoVIC should not be construed as endorsements of the company's products.

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 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 has generated 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 currently in Phase 3 clinical development targeting gram-positive *Staphylococcus aureus* (*S. aureus)* alpha-toxin in VAP patients.

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-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-401 (blood stream infections). AR-401 is a fully human mAb preclinical program aimed at treating infections caused by gram-negative *Acinetobacter baumannii*.

AR-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that are directed at multiple envelope proteins of the SARS-CoV-2 virus.

AR-712 (COVID-19). AR-712 is a cocktail of fully human mAbs (AR-711 and AR-713) that are directed against the receptor binding domain of the SARS-CoV-2 virus. It is formulated for delivery via inhalation using a nebulizer.

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, 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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