

# **Aridis Pharmaceuticals COVID mAb AR-712 Neutralizes SARS-COV2 Delta Variant**

***Texas Biomedical Research Institute and Aridis' data confirmed AR-712 binds to and neutralizes the Delta variant of SARS-COV2 virus***

***Binding analysis projects the ability of AR-712 to bind to all variants on the Center for Disease Control's Variants of Interest and Variants of Concern lists***

LOS GATOS, Calif., July 13, 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 COVID-19 mAb cocktail AR-712 binds and neutralizes the Delta variant virus SARS-COV2 at a highly effective level (~20ng/mL). Binding analyses project that AR-712 will be effective against all variants on the U.S. Center for Disease Control's Variants of Interest and Variants of Concern lists.

The dual antibody cocktail will be delivered as an inhaled treatment and is expected to provide broad coverage of all known high-risk variants. In addition, Aridis is pleased to announce the preclinical development services support from NIAID (NIH) provided further demonstration of strong therapeutic efficacy of inhaled delivery in a SARS-COV2 hamster challenge model. This achieved reversal of disease in infected animals at an inhaled dose of 1mg/kg, equivalent to a 10mg dose in humans from a nebulizer. These results confirmed the Company's efficacy studies showing highly efficient dosing by inhalation. For reference purposes, the dose of commercially available COVID antibody therapies is in the range of 500mg to 1,200mg.

AR-712 is being developed as a self-administered, at-home inhaled treatment for COVID-19 patients who are not yet hospitalized. The product candidate is designed to substantially lower the barrier to treatment of COVID-19 patients and encourage treatment much earlier in the course of their disease within the patients' own homes.

The Company remains on track to finalize the Phase 1/2/3 design for this program and initiate the clinical study in 2H 2021.

## **About AR-712**

AR-712 is a cocktail of two 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 distinct, unique molecular binding sites. The binding of SARS-COV2 spike protein RBD by AR-712 mAbs lead to effective neutralization of the live SARS-COV2 viruses in all cases tested. AR-712 comprises of AR-711 and AR-720 mAbs. AR-720 mAb is higher in potency than AR-713 and thus has replaced it in the cocktail. The AR-712 mAbs 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-720 may facilitate more rapid, broader treatment coverage, and at a substantially lower dose (>100-fold lower) as compared to parenteral administration. 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-720 extends the binding of SARS-CoV-2 strains to include all that are listed in the Variant of Interest and Variant of Concern by the U.S. Center for Disease Control (CDC). Both AR-711 and AR-720 were originally discovered through a collaboration with the University of Alabama (Birmingham) and the Texas Biomedical Research Institute.

### **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  $\Delta$ PEX™ and MablGX® 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 surface 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, 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.

**Contact:**

Investor Relations  
Jason Wong  
Blueprint Life Science Group  
jwong@bplifescience.com  
(415) 375-3340 Ext. 4

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