Aridis' AR-301 Monoclonal Antibody is Among the First Biologics to Receive FDA's Qualified Infectious Diseases Product (QIDP) Designation

- ***QIDP designation for Biologics provides FDA Priority Review status***

LOS GATOS, Calif., July 12, 2023 /GlobeNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of novel anti-infective therapies for treating life-threatening infections, today announced that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) Designation under the Generating Antibiotic Incentives Now (GAIN) Act for AR-301, a fully human IgG1 monoclonal antibody (mAb) currently in Phase 3 clinical development as an adjunctive therapy for pneumonia caused by gram-positive *Staphylococcus aureus* in critically ill hospitalized patients.

"To our knowledge, AR-301 is the very first antibacterial biologics to be awarded the QIDP designation, marking a significant milestone not only for Aridis but also for companies with biologic solutions to fighting antimicrobial resistance (AMR)," stated Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Our AR-301 program will now benefit from the FDA's priority review, in addition to previously awarded Fast-Track status, allowing for accelerated drug development and regulatory review processes. This sought-after designation positions our AR-301 program extremely well as we continue to advance it through a confirmatory Phase 3 trial and license application."

Part of the *Food and Drug Administration Safety and Innovation Act, FDASIA* (June 2012), Title VIII – *Generating Antibiotic Incentives Now* (GAIN), the QIDP designation was created to encourage the development of treatments for antibiotic-resistant organisms known to cause serious or life-threatening infections. Recently, The *Food and Drug Omnibus Reform Act of 2022* (FDORA), signed on 29-Dec-2022 as part of the *Consolidated Appropriations Act, 2023*, amends GAIN to expanded QIDP eligibility to include biological products.

An estimated one million patients annually are affected by ventilator associated pneumonia (VAP) that occurs in hospitalized patients receiving respiratory support, which is one of the most frequent ICU-acquired infections. AR-301 specifically targets *S. aureus* alpha-toxin, which has been implicated in the pathogenesis of pneumonia caused by *S. aureus* bacteria.

Aridis received positive feedback from the FDA in May 2023 on the Company's proposed single confirmatory Phase 3 study of AR-301. In addition to agreeing to the study required to support the submission of a Biologics License Application (BLA), the FDA agreed to the proposed expansion of the confirmatory Phase 3 study in *S. aureus* VAP patients to include ventilated hospital-acquired pneumonia (HAP) and ventilated community-acquired pneumonia (CAP) patients.

About Aridis Pharmaceuticals, Inc.

Aridis Pharmaceuticals, Inc. discovers and develops anti-infectives to be used as first-line treatments to combat antimicrobial resistance (AMR) and viral pandemics. 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 mAbs for therapeutic treatment of critical infections. These mAbs are already of human origin and functionally optimized by the natural human immune system for high potency. Hence, they are already fit-for-purpose and do not require further engineering 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 antibacterial and 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/HAP/CAP). AR-301 is a fully human IgG1 mAb currently in Phase 3 clinical development targeting gram-positive *S. aureus* alpha-toxin in ventilator associated pneumonia (VAP), ventilated hospital acquired pneumonia (HAP), and ventilated community acquired pneumonia (CAP) patients.

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 a Phase 2a clinical study in CF patients.

AR-320 (VAP). AR-320 is a fully human mAb targeting *S. aureus* alpha-toxin for prevention of VAP. Statistically significant Phase 2 data in the target population of those ≤ 65 years of age was published in the September 2021 Lancet Infectious Diseases journal. The Company has completed discussions with the EMA and FDA on study design and recently launched the Phase 3 study.

AR-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that target multiple sites on the spike proteins of the SARS-CoV-2 virus.

AR-101 (HAP). AR-101 is a fully human IgM mAb in Phase 2 clinical development targeting *Pseudomonas aeruginosa* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* HAP cases worldwide. This program is licensed to the Serum Institute of India and Shenzhen Arimab.

AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb directed against the F-protein of diverse clinical isolates of respiratory syncytial virus (RSV). This program is licensed exclusively to the Serum Institute of India.

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

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, 2022, 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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