Aridis Pharmaceuticals' AR-301 Eligible for Consideration under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)

- ***LPAD may provide alternative pathways for streamlined product approval***

LOS GATOS, Calif., June 20th, 2023 / Globe Newswire/ -- 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 its AR-301 clinical program has been deemed eligible for consideration under the U.S. Food and Drug Administration's (FDA) Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). The FDA's agreement signifies that the AR-301 clinical program meets the requirements for a well-defined limited population with unmet medical need as designated in the LPAD guidance.

The official determination regarding the use of the LPAD pathway will be made after the Company's request following the filing of the biologics license application (BLA).

Vu Truong, PhD, Chief Executive Officer of Aridis Pharmaceuticals, stated "We are encouraged by the FDA's recognition of AR-301's potential to address the urgent unmet medical needs of limited populations such as older adults over 65 years old. The eligibility for LPAD may provide an alternative pathway for product approval based on the available clinical data set and enable us to bring this innovative therapy to patients in need much sooner."

Eligibility for LPAD can provide more streamlined approaches, such as smaller, shorter, or fewer clinical trials, as described in the FDA's 'Antibacterial Therapies for Patients with an Unmet Medical Need for the Treatment of Serious Bacterial Diseases' guidance. Furthermore, it allows a drug approved under LPAD for certain indications to be approved under a non-LPAD pathway for other indications.

"LAPD is designed to accelerate the development and approval of novel antibacterial and antifungal drugs that address serious or life-threatening infections in limited populations with unmet needs," added Hasan Jafri, MD, Chief Medical Officer of Aridis Pharmaceuticals. "We believe that AR-301 has the potential to significantly improve the treatment landscape for such a vulnerable patient population, and we look forward to working closely with the FDA as we advance our clinical program."

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). AR-301 is a fully human IgG1 mAb currently in Phase 3 clinical development targeting gram-positive *S. aureus* alpha-toxin in VAP 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* hospital acquired pneumonia 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.

Contact:

Investor Relations
Dave Gentry, CEO
RedChip Companies
ARDS@redchip.com

SOURCE Aridis Pharmaceuticals, Inc.