Aridis Pharmaceuticals Receives Orphan Drug Designation From the European Medicines Agency for AR-501

SAN JOSE, Calif., July 19, 2019 /PRNewswire/ -- **Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS)** announced today that the European Medicines Agency (EMA) has granted Orphan Drug Designation to AR-501, the Company's inhaled formulation of gallium citrate for treatment of lung infection in patients with cystic fibrosis. This past June, Aridis also received Orphan Drug Designation for AR-501 from the U.S. Food and Drug Administration (FDA) for the same condition.

"Receiving orphan designation from the EMA for AR-501 is an important step in ensuring the program is well positioned from a global regulatory development pathway standpoint as we continue to advance its ongoing Phase 1/2a clinical trial," commented Vu Truong, PhD, Chief Executive Officer of Aridis Pharmaceuticals, Inc. "We remain on track to report data from the Phase 1 segment of the trial consisting of healthy subjects in Q1 2020 and the Phase 2a portion with cystic fibrosis subjects in Q2 2021."

Orphan Drug Designation in Europe is available to companies developing products intended to treat a life-threatening or chronically debilitating condition that affects fewer than five in 10,000 persons in the European Union (EU). This designation allows for financial and regulatory incentives that include a 10-year period of marketing exclusivity in the EU after product approval, protocol assistance from the EMA at reduced fees during the product development phase, and access to centralized marketing authorization.

Cystic fibrosis patients often suffer from severe, persistent secondary bacterial lung infections due to their underlying lung disease which results in an immune-compromised state. AR-501 is a non-antibiotic, small molecule anti-infective in which gallium functions as an iron analog that antagonizes multiple iron-dependent pathways in microbes and thus, subverts multiple key functions in bacteria. Preclinical efficacy and safety data have demonstrated that AR-501 works synergistically with multiple antibiotics, is effective against antibiotic resistant strains, and has a low intrinsic resistance profile. AR-501 is being developed as a self-administered, weekly treatment which is being evaluated in an-going Phase 1/2a clinical trial funded by the Cystic Fibrosis Foundation (ClinicalTrials.gov Identifier: NCT03669614).

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 developing a non-antibiotic novel mechanism small molecule anti-infective candidate to treat lung infections in cystic fibrosis patients. The Company also utilizes its proprietary MabIgX® technology platform to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection to produce mAbs. These mAbs are already of human origin and functionally optimized for high potency by the donor's immune system, hence they do not require genetic engineering or further optimization to achieve full functionality and high mAb productivity. MabIgX® also allows for the selection of any antibody isotype depending on the optimal effector function required for treating the target infection. By bypassing the humanization and binding sequence optimization steps, and the entire process of generation of genetically engineered antibody producing cell lines, MabIgX® enables high gross-margins and expedited progression to clinical development.

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). 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 broad spectrum antibiotics, which is the current standard of care. 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 company's pipeline is highlighted below:

Aridis' Pipeline
AR-301 (ventilator associated pneumonia). AR-301 is a fully human immunoglobulin 1, or IgG1, mAb currently in Phase 3 clinical development targeting gram-positive *S. aureus* alpha-toxin in ventilator-associated pneumonia, or VAP, patients.

AR-105 (ventilator associated pneumonia). AR-105 is a fully human IgG1 mAb targeting gram-negative *P. aeruginosa* alginate in VAP patients. AR-105 is currently being evaluated in a global Phase 2 clinical study.

AR-101 (hospital acquired pneumonia). AR-101 is a fully human immunoglobulin M, or IgM, mAb targeting *P. aeruginosa* liposaccharide serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide. A plan for the next clinical study will be communicated following the availability of Phase 2 clinical data for AR-105.

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 (CF) patients. This program is currently in a Phase 1/2a clinical study in healthy volunteers and CF patients.

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

AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb currently in preclinical development 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 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 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, 2018 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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