Aridis Pharmaceuticals Announces Publication of Positive AR-301 Phase 1/2a Data in "Intensive Care Medicine" and "The Lancet Respiratory Medicine"

- Positive safety and efficacy trends of AR-301 in Phase 1/2a clinical trial was presented at the 31st Annual Congress of the European Society of Intensive Care Medicine
- Potential breakthrough approach to the treatment of critically ill patients with pneumonia due to Staphylococcus aureus bacteria

SAN JOSE, Calif., Nov. 7, 2018 /PRNewswire/ -- **Aridis Pharmaceuticals, Inc**. (NASDAQ: ARDS), a biopharmaceutical company focused on the discovery and development of targeted immunotherapies using fully human monoclonal antibodies, or mAbs, to treat life-threatening infections, today announced that positive data from its first-in-human Phase 1/2a clinical trial of AR-301 as an adjunct to standard-of-care antibiotics for the treatment of severe pneumonia caused by *Staphylococcus aureus (S. aureus)* bacteria, was published in the October 21, 2018 issue of the *Intensive Care Medicine* journal. The article entitled "Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial," was also summarized in the October 31, 2018 online edition of *The Lancet Respiratory Medicine* in an article entitled "Safety and tolerability of AR-301 in patients with severe pneumonia". In addition, this data was presented by Dr. Pierre-Francois Laterre at the 31st Annual Congress of the European Society of Intensive Care Medicine in Paris, France.

48 patients in 13 intensive care units (ICU) in five countries, including the U.S., France, Belgium, the U.K. and Spain were enrolled and treated in this multi-center, randomized, double-blinded, placebo-controlled trial. Inclusion criteria included patients ages 18 or older with severe hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), or severe community-acquired bacterial pneumonia (CABP) caused by *S. aureus* (either methicillin-resistant *S. aureus*, or MRSA, or methicillin-sensitive *S. aureus*, or MSSA).

The results demonstrate that adjunctive treatment of severe *S. aureus* HABP in the ICU with AR-301 was well tolerated. There were few drug-related adverse events reported and the efficacy data trended toward shorter ventilation time for VABP patients and higher and faster microbiologic eradication. The authors stated that 'This innovative therapy may represent a breakthrough approach to the treatment of critically ill patients diagnosed with pneumonia due to *S. aureus*'.

"We are delighted to have had these encouraging safety and efficacy data published in *Intensive Care Medicine* and *The Lancet Respiratory Medicine, which are two of the most respected peer-reviewed journals for the intensive care and respiratory areas of medicine,"* said Vu Truong, Ph.D., Founder and CEO of Aridis. "The clinical data underscores our belief that AR-301 represents a potential exciting new approach to the treatment of critically ill patients with severe pneumonia due to *S. aureus*. A Phase 3 clinical study to evaluate the use of AR-301 in a larger population as an adjunct to standard-of-care antibiotics to improve treatment outcomes for this under-served patient population is slated to start this quarter."

The primary objective of the Phase 1/2a study was to establish the safety and tolerability of a single administration of AR-301 in patients with severe *S. aureus* pneumonia. Secondary objectives were to assess the pharmacokinetics (PK), immunogenicity, and microbiologic and clinical efficacy of AR-301.

The design was a first-in-human study with four increasing single doses of AR-301, which were administered to sequential cohorts (1, 3, 10 and 20 mg/ kg) in 8, 12, 15 and 13 patients, respectively, each cohort including 2–5 patients receiving placebo. AR-301 was administered by intravenous infusion over 2 hours starting within 36 hours following the diagnosis of severe pneumonia. After administration of AR-301, the follow-up period lasted 107 days with test-of-cure visits on day 8, 15 and 29.

About AR-301

AR-301 is a fully human monoclonal IgG1 antibody that specifically targets *S. aureus* alpha-toxin, an important virulence factor that is secreted by both methicillin-resistant *S. aureus* (MRSA) and methicillin-sensitive *S. aureus* (MSSA). AR-301 protects against alpha-toxin mediated destruction of host cells, preserving the human immune cells. AR-301's mode of action is independent of the antibiotic resistance profile of *S. aureus* and it is active against infections caused by both MRSA and MSSA.

About Aridis Pharmaceuticals, Inc.

Aridis (Nasdaq: ARDS) is a late-stage biopharmaceutical company focused on discovering and developing targeted immunotherapies using fully human monoclonal antibodies, or mAbs, to treat life-threatening

infections. The use of mAbs represents an innovative treatment approach that harnesses the human immune system to fight infections and is designed to overcome the deficiencies associated with the current standard of care, broad spectrum antibiotics. Such deficiencies include, but are not limited to, increasing drug resistance, short duration of response, perturbation of the human microbiome, and lack of differentiation among current treatments. Aridis' pipeline includes AR-301, a fully human immunoglobulin 1, or IgG1, mAb targeting hospital-acquired pneumonia, or HAP, and ventilator-associated pneumonia, or VAP, *S. aureus* alphatoxin; AR-105, a fully human IgG1 mAb being developed to treat acute pneumonia caused by *P. aeruginosa* infection; AR-101, a fully human immunoglobulin mAb targeting *P. aeruginosa* serotype O11, which accounts for approximately 22% of all P. aeruginosa hospital acquired infections worldwide; AR-501, a broad spectrum small molecule anti-infective being developed to manage both chronic lung infections in cystic fibrosis patients; AR-401, our preclinical mAb program aimed at treating infections caused by *Acinetobacter baumannii*; and AR-201, a fully human IgG1 mAb that neutralizes diverse clinical isolates of respiratory syncytial virus, or 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's expectations, strategy, plans or intentions. These forward-looking statements are based on Aridis's 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's 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's ability to attract collaborators and partners and risks associated with Aridis's 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's 10-Q for the quarter ended June 30, 2018 and Aridis's 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:

Lisa Sher
Head of Investor & Public Relations
Sherl@aridispharma.com
+1 (970) 987-2654 (Direct)

SOURCE Aridis Pharmaceuticals, Inc.
