Aridis Pharmaceuticals

Aridis Expands Research Agreement with the Cystic Fibrosis Foundation and is Awarded FDA Expedited Program Designations

- CF Foundation expands research agreement for AR-501 (for cystic fibrosis) to include additional award amount of up to $4.6 million
- FDA grants Fast-Track and QIDP Designations for AR-501, enabling future Priority Review status
- FDA clears AR-501 to initiate human clinical testing

SAN JOSE, Calif., Dec. 4, 2018 /PRNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS) today announced that the Cystic Fibrosis Foundation (CF Foundation) has more than doubled its research agreement for the clinical development of AR-501 from $2.9 million to up to $7.5 million (contingent on Aridis achieving certain milestones).

Aridis also announced that the U.S. Food and Drug Administration (FDA) has granted both Fast-Track Designation and Qualified Infectious Disease Product Designation (QIDP) for AR-501.

Additionally, the FDA cleared AR-501's Investigational New Drug Application (IND) and the Company intends to initiate the Phase 1/2a clinical trial next month.

"The additional funding will expedite clinical development and demonstrates the CF Foundation's continued support for the clinical development of AR-501," said Vu Truong, PhD, CEO of Aridis Pharmaceuticals. "Cystic fibrosis patients could benefit from a new and differentiated anti-infective treatment for their chronic lung infections. We are excited about the potential of AR-501, an inhaled form of gallium, as a more effective delivery route than intravenous (IV) administered gallium. IV gallium has already demonstrated safety and improved lung function in a CF Foundation, National Institutes of Health (NIH), and FDA funded Phase 2 clinical study," stated Dr. Truong.

"AR-501 is a novel anti-infective with a mechanism of action (MOA) involving iron acquisition and metabolism, which is very different from the MOA of antibiotics. AR-501 has the potential to offer patients more convenient dosing (once per week) vs. standard of care inhaled antibiotics (several times per day). Moreover, AR-501 diversifies our product pipeline by offering a broad-spectrum antimicrobial with a low propensity for developing drug resistance," Dr. Truong added.

Fast-Track Designation is awarded to product candidates that demonstrate the potential to address an unmet medical need. It enables more frequent interactions with the FDA review team to expedite drug development. Fast-Track product candidates could be eligible for priority review if supported by clinical data at the time of product license application.

QIDP Designation is awarded to antibacterial or antifungal product candidates for human use that are intended to treat serious or life-threatening infections caused by certain bacterial or fungal pathogens that are deemed to be a particular threat to public health. QIDP designated products have a five-year market exclusivity extension and receive priority review for the first application submitted for product approval.

"The Fast-Track and QIDP product designations provide us the means to accelerate clinical development of AR-501 and could enable us to bring this innovative drug candidate to the CF patient population more quickly. Furthermore, the CF Foundation support provides us with the resources to complete the Phase 1/2a clinical study," said Dr. Truong.

About Aridis Pharmaceuticals, Inc.

Aridis is a late-stage biopharmaceutical company focused on discovering and developing innovative anti-infectives, such as targeted immunotherapies using fully human monoclonal antibodies (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.

The most common deficiencies of antibiotics, include: propensity for drug resistance, short duration of activity, and perturbation of the human microbiome, while offering marginal differentiation among one another in safety and efficacy.

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* alphatoxin 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* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide. A Phase 2/3 clinical study is expected to initiate in 2H2019.

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 cleared to initiate a Phase 1/2a clinical study 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-201 (RSV infection). AR-201 is a fully human IgG1 mAb preclinical program aimed at neutralizing diverse clinical isolates of 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 a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof. Aridis does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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