Aridis Pharmaceuticals

Aridis Pharmaceuticals Reports Positive Preclinical Efficacy Data of a Highly Effective Inhaled Treatment Supporting a Proposed Self-Administered Therapy for COVID-19 Patients

SAN JOSE, Calif., Oct. 19, 2020 /PRNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of novel anti-infective therapies to treat life-threatening infections, today announced the development of a highly neutralizing monoclonal antibody AR-711, discovered from convalescent COVID-19 patients, that successfully eliminated all detectable SARS-CoV-2 virus in infected animals at substantially lower doses than parenterally administered (injected) COVID-19 monoclonal antibodies ("mAb"). The potency of AR-711 and its direct delivery to the lungs by inhaled administration may facilitate broader treatment coverage and dose sparing not achievable by parenteral administration.

- AR-711 is directed against the conserved receptor-binding domain (RBD) region of the original SARS-CoV2 virus and its newly emerging variants including the currently prevalent strain G614.
- AR-711 is engineered to be long-acting in blood for up to six to 12 months.
- In the animal challenge study, golden Syrian hamsters were pre-infected with SARS-CoV-2 before a single inhalation exposure of AR-711 liquid aerosols. AR-711 eliminated detectable SARS-CoV-2 virus at all dose levels tested, with the lowest lung deposited dose of 0.03 mg/kg. The detailed data is now available on BioXriv [https://www.biorxiv.org/content/10.1101/2020.10.14.339150v1].
- AR-711 is stabilized using a proprietary formulation designed to protect the mAb from the physical stresses imparted by commercial nebulizer delivery devices on protein drugs.
- An inhalable treatment that can be self-administered using a wide variety of commercially available nebulizers can facilitate broader coverage in non-hospitalized settings and at a scale not achievable using conventional inpatient IV infusion treatments.

"As we expected, combining a highly potent monoclonal antibody with direct delivery to the lungs, which is the main target of the COVID-19 virus, achieved impressive efficacy in these animal models. The therapeutic dose that we observed corresponds to an estimated adult human equivalent efficacious inhaled dose of 2 to 6 milligrams (mg) per dose. This compares very favorably to other clinical stage COVID-19 mAbs, where up to 8,000 mg are being studied to achieve clinical benefit," said Hasan Jafri, M.D., Chief Medical Offer of Aridis.

"Over 90% COVID-19 symptomatic patients are home bound, under quarantine, and often not treated. While these patients wait, their health can deteriorate, and they could infect those around them. Having a convenient way to self-medicate with the simplicity of an asthma inhaler where the drug is delivered directly to the infection site can have a transformative impact on patients' lives, expand treatment coverage, and ultimately reduce global transmissibility," said Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals.

"Given the attractive human safety data of anti-infective mAbs and our strong preclinical efficacy as a therapeutic treatment, we plan to evaluate the therapeutic treatment using AR-711 in non-hospitalized mild to moderate COVID-19 patients in a global study to be launched in the first half of next year," said Dr. Jafri.

"The exceedingly low drug dose that achieved therapeutic efficacy is particularly exciting, as it provides a unique opportunity to meaningfully reduce treatment costs and hospitalization burden at a potential magnitude not previously achievable with mAb therapies. We are excited to bring an entirely new treatment paradigm to the COVID-19 fight," commented Vu Truong.

About AR-711
AR-711 is a fully human immunoglobulin 1, or IgG1, monoclonal antibody discovered from screening the antibody secreting B-cells of convalescent COVID-19 patients. AR-711 exhibits high affinity for SARS-CoV-2 spike protein, approximately 10-fold or higher than mAb candidates currently in late stage clinical testing. AR-711 was previously shown to be effective in prophylactic as well as therapeutic treatment modes in a SARS-CoV-2 viral challenge study. AR-711 was discovered at the University of Alabama at Birmingham and Texas Biomedical Research Institute (originally known as mAb '1212C2'), recently licensed and is currently being developed by Aridis as an inhaled, self-administered treatment for non-hospitalized patients suffering from mild to moderate COVID-19. AR-711 is also one the two mAbs in the company's AR-701 mAb cocktail, which is a separate program being developed as an intravenous treatment of moderate to severe, hospitalized COVID-19 patients.

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 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 monoclonal antibody (mAbs) for therapeutic treatment of critical infections. These mAbs are already of human origin and functionally optimized for high potency by the donor's immune system; hence, they technically do not require genetic engineering or further 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 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:

About ʎPEX™ Technology Platform
Aridis utilizes its ʎPEX technology platform for the unbiased discovery of new and highly potent antibodies against pathogens including COVID-19. The ʎPEX platform is comprised of a silicon wafer-based array of nanoliter sized tissue micro-culture wells that enable rapid screening of antibody secreting cells, enabling discovery of potent antibodies against targets such as SARS-CoV-2, the virus that causes COVID-19 disease within a few days of patient sample availability. It also features CRISPR enabled activation of endogenous genetic control elements that dramatically increase the yield of such therapeutic antibodies from manufacturing production cell lines. The technology also features a proprietary production cell line that is designed to rapidly manufacture multiple monoclonal antibody therapeutics at approximately half the manufacturing cycle time than currently available manufacturing technologies.

Aridis' Pipeline
AR-301 (VAP). AR-301 is a fully human IgG1 mAb currently in Phase 3 clinical development targeting gram-positive *Staphylococcus aureus* (*S. aureus)* alpha-toxin in VAP patients.

AR-101 (HAP). AR-101 is a fully human immunoglobulin M, or IgM, mAb in Phase 2 clinical development targeting *Pseudomonas aeruginosa* (*P. aeruginosa)* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide.

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 1/2a clinical study in healthy volunteers and 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-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that are directed at multiple envelope proteins of the SARS-CoV-2 virus.

AR-711 (COVID-19). AR-711 is an in-licensed mAb that is directed against the receptor binding domain of the SARS-Cov 2 virus. The agent has the potential to be delivered both intravenously and by inhalation using a nebulizer.

AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb out-licensed preclinical program 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 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, 2019 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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