



Aridis Provides Corporate Update

LOS GATOS, Calif., June 24, 2024 /GlobeNewswire/ -- Aridis Pharmaceuticals, Inc. (OTC: ARDS) ("Aridis" or the "Company"), a biopharmaceutical company, today announced a corporate update on recent developments.

The Company has been in sustained discussions with other pharmaceutical companies and investment firms on possible partnerships and investments on its clinical product candidates AR-301, AR-320, AR-501, and the APEX platform technology. The principal goal for the discussions has been to build shareholder value by out-licensing or attracting capital investments to complete the final stages of product development. A summary of the status of the major programs is further highlighted below:

Lead product candidate AR-301

- The Company believes that the observed consistency of positive clinical efficacy trends and the magnitude of clinical response associated with AR-301 treatment observed in older patients in the first Phase 3 study underscore the need for its continued development.
- The discussions with potential partners to continue the development of AR-301 are expected to reach a definitive outcome in the 4th quarter.

Development status: AR-301 is currently being evaluated for the adjunctive therapeutic treatment of Ventilator Associated Pneumonia (VAP). The first of two planned Phase 3 clinical trials saw significant reduction in patient enrollment that was brought about by the COVID-19 pandemic, resulting in an under-powered study. However, despite a small sample size, a positive efficacy trend in favor of AR-301 in VAP patients was observed ($p=0.242$ at day 21). Remarkably, in a prespecified subpopulation of adults 65 years and older, the efficacy signal was increased by approximately 300%, reaching statistical significance level ($p=0.056$ at day 21 and $p=0.025$ at day 28 post-treatment). Furthermore, AR-301 treated patients had a median reduction of length of stay in the intensive care unit (ICU) and hospital by 7 days and by 9 days in the over 65 subpopulation. The clinical data and the proposed design for the second and final Phase 3 study were presented to the FDA and the European Medicines Agency (EMA). Concurrence has been achieved with the regulators on a single, globally harmonized Phase 3 study for licensure.

Phase 3 product candidate AR-320

- In the past year the Company has diligently explored paths toward a potential resolution of its product licensing dispute with MedImmune Limited ("MedImmune", a subsidiary of AstraZeneca).

- The Company expects to settle on a definitive path forward in the next quarter.

Development status: AR-320 is being developed for the prevention of Ventilator Acquired Pneumonia (VAP) in a pivotal Phase 3 clinical trial. The AR-320-003 Phase 3 clinical study was initiated in 2022, with 24 patients enrolled. The study was placed on voluntary hold at the time - the product license dispute with MedImmune arose and continues to be on hold while the Company continues to explore potential resolutions.

Phase 2 product candidate AR-501

- The recent demonstration in Phase 2a that the study met its primary and secondary endpoints in cystic fibrosis (CF) patients has facilitated business development discussions with potential pharmaceutical partners
- The positive clinical trial data also facilitated the filing of non-dilutive grant funding support from governmental sources and non-governmental organizations (NGO).

Development status: AR-501 is being developed as a therapeutic treatment for chronic bacterial lung infections in cystic fibrosis patients. A Phase 1 trial in healthy adults and a Phase 2a trial in cystic fibrosis patients were completed. The primary endpoint of safety was achieved in both studies, showing that AR-501 was well tolerated when administered as an inhaled dosage form over several weekly treatments. The pharmacokinetic data showed effective delivery of AR-501 into the lungs of CF patients and a fast clearance rate.

Company operations and financials

The Company's primary focus in the past year has been on business development discussions related to its clinical product candidates, on laboratory activities to support two NIH active grant awards and on one funded external collaboration related to the APEX platform technology. Operating expenses, including clinical trial and clinical supplies manufacturing have been significantly lowered while the AR-320-003 trial has been on hold. The Company has been working with its lead lender Streeterville Capital, LLC to service the loan via equity exchange agreements. The Company's near-term goals will be to successfully complete the business objectives described above and to become current on its SEC filings in the coming quarter.

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 advancing multiple clinical stage monoclonal antibodies (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 current standard-of-care 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 Company's mAb portfolio is complemented by a novel non-antibiotic small molecule anti-infective candidate mechanism 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 targeting gram-positive *Staphylococcus aureus* (*S. aureus*) alpha-toxin that has recently completed the first of two planned Phase 3 superiority clinical studies as an adjunctive treatment of *S. aureus* ventilator associated pneumonia (VAP).

AR-320 (VAP). AR-320 is a fully human IgG1 mAb targeting *S. aureus* alpha-toxin that is being evaluated in a Phase 3 clinical study as a preventative treatment of *S. aureus* colonized mechanically ventilated patients who do not yet have VAP.

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 has successfully completed Phase 2a clinical development in CF patients.

AR-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that are directed at multiple protein epitopes on the SARS-CoV-2 virus. It is formulated for delivery via intramuscular injection or inhalation using a nebulizer.

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-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 (HAP) cases worldwide.

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/>. [I haven't reviewed the website, but you'll want to be sure there are no inconsistencies with this release]

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.

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