

Aridis Pharmaceuticals Expands Phase 2a Trial Into the U.S. for Monoclonal Antibody AR-301 for the Treatment of Acute Pneumonia

SAN JOSE, Calif. – July 8, 2015 – [Aridis Pharmaceuticals, Inc.](#), a biopharmaceutical company applying proprietary technologies to produce novel anti-infectives and immunotherapies for infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for AR-301, also referred to as Salvecin™, the company's fully human anti-*Staphylococcal* α -toxin IgG₁ monoclonal antibody being developed for the treatment of hospital-acquired and ventilator-associated pneumonia (HAP and VAP) caused by *Staphylococcus aureus*, including multi-drug resistant 'MRSA' strains. Acceptance of the IND application enables Aridis to expand and accelerate its current Phase 2a study of AR-301 as an adjunctive therapy with standard-of-care antibiotics into the United States. The study is currently underway in three European countries, with further expansion into the United Kingdom also planned. Top-line results from the accelerated Phase 2a study are expected in the first half of 2016.

Paul-Andre de Lame, M.D., Chief Medical Officer of Aridis, stated, "We are looking forward to expanding the Phase 2a trial of AR-301, our second most advanced product candidate, into the United States. We believe AR-301 can positively impact the outcome of *S. aureus* infections by improving survival rates and/or shortening the time a patient spends in the intensive care unit (ICU), or overall hospital stay."

Vu Truong, Ph.D., founder and Chief Executive Officer, added, "This is important because we believe it could potentially save thousands of lives per year and significantly reduce hospital infrastructure-related costs. We look forward to completing this study and reporting top-line results in the first half of 2016."

The European Phase 2a clinical trial is a randomized, double-blind, placebo-controlled, single ascending dose study to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of a single intravenous administration of AR-301 in patients with severe pneumonia caused by *S. aureus*. Depending on the outcome of Phase 2a clinical trial, Aridis expects the subsequent phase of clinical testing of AR-301 to be either a Phase 2b trial, followed by a Phase 3 trial in pneumonia patients.

AR-301 was discovered by screening B-cell lymphocytes of a patient with confirmed *S. aureus* infection and developed using Aridis' proprietary MAbIgX® technology. It binds and neutralizes *S. aureus* alpha toxin, preventing alpha toxin-mediated destruction of human cells. There is no anti-infective on the market that specifically neutralizes the pathogenic effects brought about by *S. aureus* toxins and Aridis believes that this mechanism of action complements the bacterial killing properties of many conventional antibiotics, as the bacterial toxins left behind following antibiotic-mediated killing can still be neutralized by AR-301.

About AR-301 (Salvecin™)

AR-301, also referred to as Salvecin™, is a fully human immunoglobulin G1, or IgG1, mAb targeting Gram-positive *Staphylococcus aureus*, or *S. aureus*, bacteria, including multi-drug resistant *S. aureus* ('MRSA'), which is currently in a Phase 2a clinical trial in HAP and VAP patients. The clinical study is a randomized, double-blind, placebo-controlled study in 52 patients comparing the safety and efficacy of AR-301 as adjunctive therapy with standard-of-care antibiotics versus antibiotics alone. AR-301 is designed to be effective on bacterial infections whether or not they are resistant to conventional antibiotics. Salvecin™ has already demonstrated strong prophylactic and therapeutic efficacy in mouse models of *S. aureus* pneumonia. Salvecin™ has also been granted Orphan Drug designation in the European Union (EU).

About Acute Pneumonia Due to *Staphylococcus aureus*

HAP/VAP due to methicillin-resistant *Staphylococcus aureus*, or MRSA, infections results in substantial loss of life with an annual US/EU/Japan incidence of approximately 523,000 patients and mortality rates as high as 50% depending on the patient population and treatment regimen (Methicillin-Resistant *Staphylococcus Aureus*, Decision Resources, November 2010). Infections due to MRSA represent a high-value segment of the overall antibiotics market, which is projected to continue expanding. According to this report, the worldwide market for existing therapies for MRSA infections was \$630 million in 2009 and is projected to increase to \$752 million by 2019. This increase will be driven partly by the progressively aging population, which is expected to increase the number of MRSA infections that result in HAP. Moreover, MRSA infections are associated with significantly longer hospital stays, repeated hospitalizations and increased healthcare costs. Currently, the average hospital stay of a patient with HAP/VAP is ten to 20 days, and the average length of ICU stay is five to ten days. We believe the economic impact of HAP can be calculated in terms of an average cost of hospital stay of \$25,000 to \$50,000.

About Aridis Pharmaceuticals, Inc.

Aridis is a privately held biopharmaceutical company applying proprietary monoclonal antibody discovery technology MAbIgX® and pharmaceutical formulation technologies to produce novel infectious disease focused therapies. Aridis' product pipeline includes AR-101 anti-*Pseudomonas aeruginosa* LPS human monoclonal antibody; AR-301 anti-*Staphylococcus aureus* human monoclonal antibody to treat acute pneumonia; Aerucin™, a broadly reactive monoclonal antibody against *Pseudomonas aeruginosa* initially being developed to treat acute pneumonia; Panaecin™, a small molecule anti-infective gallium compound with broad spectrum activities against bacteria, viruses, and fungi; AR-401 anti-*Acinetobacter baumannii* human monoclonal antibody; and AR-201 anti-RSV human monoclonal antibody.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements relating to the therapeutic applications of AR-101, AR-301, Aerucin™, Panaecin™, AR-401, AR-201, Aridis' proprietary formulation and delivery technologies, about Aridis' strategy, pre-clinical and clinical programs, and ability to identify and develop drugs, as well as other statements that are not historical facts. Actual events or results may differ materially from Aridis' expectations. Factors that could cause actual results to differ materially from the

forward-looking statements include, but are not limited to, the timing, success and cost of Aridis' research and clinical studies and its ability to obtain additional financing. These forward-looking statements represent Aridis' judgment as of the date of this release. Aridis disclaims any intent or obligation to update these forward-looking statements.

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