

Aridis Pharmaceuticals Receives FDA Fast Track Designation for AR-301 for Acute Pneumonia caused by *Staphylococcus aureus*

SAN JOSE, Calif. – September 11, 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) granted Fast Track Designation to AR-301, the Company's fully human anti-*Staphylococcal* alpha-toxin IgG₁ monoclonal antibody (mAb). AR-301 is currently in Phase 2a clinical trial for the treatment of hospital-acquired and ventilator-associated pneumonia (HAP and VAP) caused by *Staphylococcus aureus*, including multi-drug resistant "MRSA" strains.

Vu Truong, Ph.D., Founder and CEO of Aridis, stated, "This is our second product candidate to receive FDA Fast Track designation this year, which provides an accelerated development and regulatory review pathway. Together with Aerucin™, our broadly active human IgG₁ mAb against *P. aeruginosa*, these innovative mAbs provide a significant opportunity to improve patient outcomes from potentially life-threatening infections caused by two of the most common and difficult to treat pathogens. We recently expanded our ongoing Phase 2 trial of AR-301 into the U.S. and expect to complete patient enrollment in the first half of 2016, and in parallel, our Phase 1 trial of Aerucin™ remains on track for completion in the fourth quarter of this year. We look forward to achieving these significant milestones as we continue to execute our clinical development strategy."

Fast Track designation is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill unmet medical needs. Companies that receive Fast Track designation are allowed to submit New Drug Applications (NDA) or Biologics License Applications (BLA) on a rolling basis, expediting the FDA review process, and benefiting from more frequent communication with the FDA to discuss all aspects of clinical development. Additionally, drugs that receive Fast Track designation are eligible for accelerated approval and priority review.

About AR-301

AR-301 is a fully human immunoglobulin G₁, or IgG₁, mAb targeting Gram-positive *Staphylococcus aureus*, or *S. aureus*, bacteria, including methicillin-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. AR-301 has already demonstrated strong prophylactic and therapeutic efficacy in mouse models of *S. aureus* pneumonia and has also been granted Orphan Drug designation in the European Union (EU).

About Acute Pneumonia Due to *S. aureus*

HAP/VAP due to methicillin-resistant *Staphylococcus aureus* (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. Aridis believes 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® 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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