Aridis Pharmaceuticals

Aridis Pharmaceut Suvratoxumab, a P from AstraZeneca

LOS GATOS, Calif., July 19, 2021 /PRNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS) today announced that it has entered into an exclusive, worldwide licensing agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) to in-license the late stage monoclonal antibody candidate, suvratoxumab.

The highlights of the agreement are:

- **Phase 3-ready candidate.** Suvratoxumab monoclonal antibody (mAb) for prevention of pneumonia has been licensed from AstraZeneca. Suvratoxumab extends Aridis' pneumonia franchise by complementing the existing AR-301 Phase 3 pneumonia treatment program.
- **Lancet ID publication.** Phase 2 data involving n=196 patients recently published in The Lancet Infectious Diseases journal showed safety and a statistically significant (47%) relative reduction of pneumonia in *S. aureus* colonized, mechanically ventilated patients less than 65 years old, with corresponding reduction in the number of days needed in the ICU and hospital.[i]
- **Up to €25 million Euros funding (approximately $30 million).** EU Commission's Innovative Medicines Initiatives (IMI) funding for suvratoxumab Phase 3 clinical trial
- **AstraZeneca's equity stake in Aridis.** AstraZeneca becomes a shareholder of Aridis through the issuance of common stock and has right of first negotiation for future licensing of suvratoxumab.

Monoclonal Antibody	**Targeting**	**Disease**	**Development Status**	**Next Milestone**
suvratoxumab or 'AR-320'	*Staphylococcus aureus* alpha toxin	*S. aureus* colonized patients at high risk of developing pneumonia	Phase 2 completed	Phase 3 launch 4Q-2021

Deal Highlights

• Aridis acquires global exclusive rights for development and commercialization of suvratoxumab for all indications
• AstraZeneca retains rights of first negotiation for future licensing
• Aridis will make an upfront payment to AstraZeneca of $11m in cash and Aridis common stock. AstraZeneca will also receive up to a further $115m on achievement of certain development and sales-related milestones, in addition to tiered royalties on net sales
• Up to €25 million Euros (approximately $30m) from EU Commission's Innovative Medicines Initiative (IMI) COMBACTE clinical trial consortium for the Phase 3 trial for suvratoxumab

Development Overview: Suvratoxumab Phase 3 Clinical Study
Suvratoxumab and AR-301 are complementary products. Suvratoxumab's focus on preventive treatment of *S. aureus* pneumonia complements Aridis' AR-301 Phase 3 mAb program which is being developed as a

therapeutic treatment of *S. aureus* pneumonia.

A multinational, randomized, double blinded, placebo controlled Phase 2 study (n=196 patients) showed that mechanically ventilated ICU patients colonized with *S. aureus* who are treated with suvratoxumab saw a relative risk reduction of pneumonia by 32% in the overall intend to treat (ITT) study population, and by 47% in the under 65 year old population, which is the target population in the planned Phase 3 study. The relative risk reduction in the target population reached statistical significance, and was also associated with a substantial reduction in the duration of care needed in the ICU and hospital.[i] [see https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30995-6/fulltext]

Aridis believes that suvratoxumab (product code name 'AR-320') will be first-line treatment, first to market, first-in-class pre-emptive treatment of *S. aureus* colonized patients. The same first-line, first to market and first-in-class strategy applies to the acute treatment with the monoclonal antibody AR-301 which the Company believes makes Aridis a globally dominant leader in this space.

Aridis comments
"We are pleased to have been selected as AstraZeneca's licensee. The strong data from the Phase 2 trial gives us an advantage to define the patient population, primary endpoint, and the Phase 3 clinical study design to support a clear path to the Phase 3 confirmatory trial," said Vu Truong, Ph.D., Aridis' Chief Executive Officer.

"We intend to efficiently leverage our collaboration with the globally renowned HAP/VAP experts in the EU Commission's Innovative Medicines Initiative (IMI) COMBACTE consortium and our global network of existing clinical sites to launch the Phase 3 study for AR-320 in the 4th quarter this year," said Hasan Jafri, M.D., Aridis' Chief Medical Officer. "We are delighted that this Phase 3-ready candidate is supported by IMI through the COMBACTE consortium and are excited to demonstrate the potential for suvratoxumab to fulfill an unmet medical need in a highly vulnerable and high-risk population, while also offering substantial pharmacoeconomic benefits," said Dr. Jafri.

AstraZeneca comments
Mark Esser, Vice President, Microbial Sciences, BioPharmaceuticals R&D, AstraZeneca said:
"Suvratoxumab has the potential to transform pulmonary infection management in ventilated patients. We are pleased to complete this licensing deal with Aridis who we believe are well placed to take suvratoxumab forward."

IMI's COMBACTE consortium comments
"On behalf of IMI's COMBACTE consortium, I would like to express our continued support and strong enthusiasm for suvratoxumab," said Dr. Marc JM Bonten, MD/PhD, Managing Entity and Scientific and Academic coordinator of COMBACTE (University Medical Center, Utrecht). "We plan to leverage the consortium's vast network of clinical sites and principal investigators across Europe to facilitate the execution of this important Phase 3 study to its timely completion," said Dr. Bonten.

Dr. Bruno Francois, a world renowned VAP expert and the Academic COMBACTE Lead for the Phase 3 study (University Hospital of Limoges) further added, "After the very promising SAATELLITE phase 2 trial, starting this phase 3 is very exciting as it could bring a new class of molecules to treat severe bacterial infections, to patients. The COVID pandemic has highlighted the importance of having therapeutic options to address emerging infectious threats and antimicrobial resistance (AMR) remains a serious threat. In this context, the AR-320 study is very timely. Lastly, the public-private partnership approach which made the phase 2 study successful, will undoubtedly be one of the major strengths of the coming phase 3 study."

About suvratoxumab ('AR-320')

Suvratoxumab (also referred to as MEDI4893) is a fully human, half-life extended IgG1 monoclonal antibody targeting *S. aureus* alpha toxin. Alpha-toxin is a key virulence factor that is secreted by both methicillin-resistant *S. aureus* (MRSA) and methicillin-susceptible *S. aureus* (MSSA). It is believed that AR-320 protects against alpha-toxin mediated destruction of host cells, preserving the human immune cells. AR-320's mode of action is independent of the antibiotic resistance profile of *S. aureus* and it is active against infections caused by both MRSA and MSSA.

About IMI's COMBACTE Consortium
The European Commission's Innovative Medicines Initiative (IMI) is the world's biggest public-private partnership in the life sciences, whose goal is to develop next generation vaccines, medicines and treatments, such as new antibiotics [see https://www.imi.europa.eu/]. The IMI-funded COMBACTE project aims to give antibiotic drug development a much-needed boost by pioneering new ways of designing and implementing efficient clinical trials for novel antibiotics. COMBACTE forms part of the New Drugs for Bad Bugs (ND4BB) initiative, IMI's wider program to tackle AMR. The COMBACTE consortium comprises a large network of over 1,000 hospitals in Europe that are potential clinical sites for clinical trial conduction [see https://www.imi.europa.eu/projects-results/project-factsheets/combacte-net]

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 ⅄PEX™ 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 antibodies (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 and respiratory viruses that cause life-threatening infections such as pneumonia, bacteremia, and COVID-19. 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:

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 Phase 2a clinical development 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-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-712 (COVID-19). AR-712 is a cocktail of fully human mAbs (AR-711 and AR-720) that are directed against the receptor binding domain of the SARS-CoV-2 virus. It is formulated for delivery via 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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[i] François B, Jafri HS, Chastre J et al. Efficacy and safety of suvratoxumab for prevention of Staphylococcus aureus ventilator-associated pneumonia (SAATELLITE): a multicentre, randomised, double-blind, placebo-controlled, parallel-group, phase 2 pilot trial. Lancet Infectious Diseases. 2021. https://doi.org/10.1016/S1473-3099(20)30995-6

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