Arsanis Announces First Patient Dosed in Global Phase 2 Study of ASN100 for Prevention of *Staphylococcus Aureus* Pneumonia

Study to evaluate safety and efficacy of ASN100 in high-risk, mechanically ventilated ICU patients

WALTHAM, Mass. and VIENNA, Austria – January 24, 2017 – Arsanis, Inc., a clinical-stage biopharmaceutical company developing targeted monoclonal antibodies (mAbs) for pre-emptive and post-infection treatment of serious infectious diseases, today announced that the first patient was dosed in a Phase 2 clinical study of its lead program, ASN100. The primary objective of this study is to evaluate the safety, tolerability, and efficacy of a single dose of ASN100 versus placebo for the prevention of *Staphylococcus aureus* pneumonia in high-risk, mechanically ventilated patients.

S. aureus causes serious and life-threatening infections, including pneumonia and bacteremia, and the incidence of healthcare-related *S. aureus* pneumonia among hospitalized patients is increasing.[1,2,3] Patients in the ICU receiving mechanical ventilation are at increased risk for *S. aureus* pneumonia, which has an overall mortality rate of approximately 30% in these patients despite antibiotic treatment.[4] ASN100, a combination of two human monoclonal antibodies (mAbs), ASN-1 and ASN-2, uniquely disarms *S. aureus* by broadly neutralizing the six cytotoxins key to the pathogenesis of pneumonia.

"The Phase 2 trial initiation follows a recently completed Phase 1 safety, tolerability and pharmacokinetic study of ASN100 in healthy volunteers in which data demonstrated half-lives for both ASN-1 and ASN-2 of at least 3 weeks, penetration of both ASN-1 and ASN-2 into bronchial alveolar lavage fluid out to 30 days, and a safety profile that is consistent with fully human monoclonal antibodies," said Chris Stevens M.D., chief medical officer at Arsanis Inc. "*S. aureus* pneumonia is an increasing public health threat with a surprising mortality rate despite available antibiotic therapies. Therefore, preventative approaches with monoclonal antibody products that neutralize the virulence of *S. aureus* are ideally suited for patients at high risk for *S. aureus* pneumonia."

In the Phase 2 study, mechanically ventilated patients at high risk for *S. aureus* pneumonia will be randomized to receive a single dose of ASN100 or placebo. Patients will be evaluated for the development of pneumonia for up to 21 days after dosing. Arsanis plans to enroll approximately 350 patients across 60 sites around the world, including the United States and Europe.

"We believe targeted, precision monoclonal antibody therapies are advantageous for the prevention and treatment of infectious diseases while avoiding antibiotic resistance. ASN100 aligns with the medical and scientific field's desire and need to move from broad-spectrum antibiotics toward prevention in patients that are at high risk of developing infection," said Rene Russo, Pharm.D., BCPS, chief executive officer, Arsanis. "Initiating the ASN100 Phase 2 study brings us closer to potentially providing this targeted solution for patients who are especially vulnerable to developing *S. aureus* pneumonia."

More information about the study is available at www.clinicaltrials.gov

About ASN100

ASN100 is a combination of two fully human monoclonal antibodies that collectively neutralize six important *S. aureus* cytotoxins associated with pneumonia pathogenesis. ASN-1 neutralizes alpha-hemolysin (Hla), a key *S. aureus* toxin responsible for lung epithelial cell damage, in addition to four *S. aureus* leukocidins responsible for lysis of human phagocytic (immune) cells: Panton-Valentine leukocidin (PVL), leukocidin ED, and gamma-hemolysins AB and CB. ASN-2 inactivates another *S. aureus* leukocidin, LukGH, which is a particularly potent human cytotoxin that is also responsible for lysis of human phagocytes. ASN100 is being evaluated in a Phase 2 clinical study for the prevention of *S. aureus* pneumonia in high-risk patients, and has received Fast Track designation from the US FDA.

About Arsanis, Inc.
Arsanis is a clinical-stage biotechnology company leading the development of targeted monoclonal antibodies (mAbs) for pre-emptive therapy and treatment of serious infectious diseases. The company's current programs address pathogenic processes selectively, rather than aiming to broadly eliminate bacteria, potentially allowing Arsanis to address critical infections without contributing to the problem of antibiotic resistance. The company is building a broad product pipeline addressing the most important Gram-positive and Gram-negative bacterial pathogens threatening hospitalized and high-risk patients. Its lead clinical program, ASN100, is aimed at serious *Staphylococcus aureus* infections and is being evaluated in a Phase 2 clinical study for the prevention of *S. aureus* pneumonia in high-risk patients.

Arsanis is a U.S. company headquartered in Waltham, Massachusetts, with European research and preclinical development operations headquartered in Vienna, Austria (Arsanis Biosciences GmbH). For more information, please visit the Arsanis website at www.arsanis.com.

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