Arsanis Presents Phase 1 and Preclinical Pharmacokinetic Data on Lead Product Candidate, ASN100, at IDWeek™ 2017

-- ASN100 rapidly penetrates into lung epithelial fluid after a single intravenous dose and was detected out to 30 days in healthy volunteers --

WALTHAM, Mass. and VIENNA, Austria – October 9, 2017 – Arsanis, Inc., a clinical-stage biopharmaceutical company focused on applying monoclonal antibody immunotherapies to address serious infectious diseases, today announced that the company presented pharmacokinetic data from a Phase 1 clinical trial in healthy volunteers and from a preclinical model of *Staphylococcus aureus* pneumonia for its investigational lead product candidate, ASN100, which is currently in a Phase 2 clinical trial for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. These data were described in three poster presentations at IDWeek™ 2017, taking place in San Diego from October 4 – 8.

"The clinical and preclinical data presented at IDWeek 2017 continue to build on a growing body of evidence supporting the development of our lead candidate, ASN100, as a potential first-in-class monoclonal antibody therapeutic with a non-antibiotic mechanism of action," said Chris Stevens, M.D., Chief Medical Officer of Arsanis. "We previously reported that in its first-in-human Phase 1 clinical trial, ASN100 was well tolerated and no dose-limiting toxicities were observed. At IDWeek, we reported additional data from this trial confirming that significant lung concentrations of ASN100 were detected in lung epithelial lining fluid (ELF) of healthy volunteers within 1 day and out to 30 days after dosing. We believe that this is the first report of an intravenously administered human IgG1 mAb measured in ELF in humans. In addition, we presented results from the ASN100 Phase 1 population PK model. Together these data support the single dose regimen in our ongoing Phase 2 clinical trial. We also reported ASN100 data in a rabbit model of *S. aureus* pneumonia in which ASN100 mAbs demonstrated rapid penetration into ELF in both uninfected and *S. aureus* infected animals, and induced dose-dependent protection from lethal pneumonia and improved tissue pathology across multiple strains tested."

Summary of Posters

Serum and Lung Pharmacokinetics of ASN100, a Monoclonal Antibody Combination for the Prevention and Treatment of Staphylococcus aureus *Pneumonia. Poster #1025.*

Twelve healthy volunteers received ASN100 open-label at doses of 3600 mg or 8000 mg. Each subject underwent two bronchoalveolar lavage (BAL) samplings either on days 1 and 30 or on days 2 and 8 post-dosing. A dose proportional increase in serum peak and exposure (AUC) of ASN100 mAbs ASN-1 and ASN-2 was observed, with an approximate half-life for each antibody of 3 weeks. Penetration of ASN-1 and ASN-2 into the lung ELF was observed at the first post-dose time point of 24 hours and both mAbs remained detectable at significant lung concentrations at day 30 post-dose.

Population Pharmacokinetic Model for Intravenous ASN100 in Healthy Subjects. Poster #1849.

Pharmacokinetic data from a previously reported ASN100 Phase 1 trial were incorporated into a two-compartment physiologic based pharmacokinetic (PK) model. This population PK model simulated various ASN100 dosing regimens to support dose selection for the ongoing Phase 2 clinical trial.

Prevention of Lung Pathology and Mortality in Rabbit Staphylococcus aureus *Pneumonia with Cytotoxin-Neutralizing Monoclonal IgGs that Penetrate Epithelial Lining Fluid. Poster #1844.*

ASN100 was tested in a rabbit model of the prevention of lethal *S. aureus* pneumonia. ASN100 at an intravenous dose of 5 or 20 mg/kg afforded 100% survival in rabbits across all four *S. aureus* strains

tested. The ASN100 mAbs rapidly penetrated the lung ELF in uninfected and *S. aureus* infected animals, reaching peak levels at 48 hours post dose. Importantly, free ASN-1 and ASN-2 serum and ELF levels were not depleted in the lungs of *S. aureus* infected rabbits despite the presence of bacteria for up to three days post challenge.

About ASN100

ASN100 is a combination of two co-administered fully human monoclonal antibodies (mAbs), ASN-1 and ASN-2 that together neutralize the six cytotoxins critical to *S. aureus* pneumonia pathogenesis. ASN-1 neutralizes alpha-hemolysin (Hla), a cytotoxin that damages lung epithelial cells, and four leukocidins, cytotoxins that destroy human immune cells: gamma-hemolysin AB (HlgAB), gamma-hemolysin CB (HlgCB), Panton-Valentine leukocidin (PVL), and leukocidin ED (LukED). ASN-2 neutralizes the fifth leukocidin, LukGH, a particularly potent human cytotoxin also responsible for the destruction of human immune cells. ASN100 is currently in a Phase 2 clinical trial for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients, and has received Fast Track designation from the U.S. Food and Drug Administration (FDA).

About Arsanis, Inc.

Arsanis, Inc. is a clinical-stage biopharmaceutical company focused on applying monoclonal antibody (mAb) immunotherapies to address serious infectious diseases. A deep understanding of the pathogenesis of infection, paired with access to some of the most advanced mAb discovery techniques and platforms available today, has positioned Arsanis to build and advance a pipeline of novel mAbs with multiple mechanisms of action and high potency against their intended targets. The company's lead clinical program, ASN100, is aimed at serious *Staphylococcus aureus* infections and is being evaluated in a Phase 2 clinical trial for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. In addition to ASN100, its preclinical pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including respiratory syncytial virus, or RSV.

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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