



## **Arsanis Receives FDA Fast Track Designation for ASN100 for the Prevention of *Staphylococcus aureus* Pneumonia**

**WALTHAM, Mass. and VIENNA, Austria – December 1, 2016** – 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ASN100 for the prevention of *Staphylococcus aureus* pneumonia in mechanically ventilated patients who are at high risk for *S. aureus* pneumonia.

Fast Track designation is intended to facilitate the development and expedited FDA review of drugs to treat serious or life-threatening conditions and address unmet medical needs.

“Despite current antibiotic treatments, *S. aureus* pneumonia has a mortality rate as high as 30 percent in this patient population<sup>1</sup>,” said René Russo, Pharm.D., BCPS, Chief Executive Officer, Arsanis. “We are pleased that the FDA has granted Fast Track designation to ASN100 to prevent *S. aureus* pneumonia in high-risk, mechanically ventilated patients, and we look forward to working closely with the Agency as we continue the development of our lead monoclonal antibody program for this vulnerable patient population.”

### **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: the Pantone-Valentine leukocidin (PVL), leukocidin ED, and gamma hemolysins AB and CB. ASN-2 inactivates the remaining *S. aureus* leukocidin, LukGH, which is a particularly potent human cytotoxin that is also responsible for lysis of human phagocytes. Arsanis has recently completed a Phase 1 clinical study of ASN100, and plans to begin dosing patients in a Phase 2 study in 2016.

### **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. Arsanis expects to initiate a Phase 2 study of ASN100 in 2016.

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](http://www.arsanis.com).

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<sup>1</sup>Kollef M. “Epidemiology and Outcomes of Health-Care-Associated Pneumonia.” CHEST. 2005 Dec;128(6):3854-62.