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Ashlea Kosikowski, Pure Communications
(910) 547-7093

Achaogen Data Show Rapid Rise in Rates of Resistance to Current Antibiotics; Illustrate Global Need for New, Well-Tolerated Agents to Address Varied Mechanisms of Resistance

Data Presented at European Congress of Clinical Microbiology and Infectious Diseases

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Achaogen, a clinical stage biopharmaceutical company addressing the issue of multi-drug resistant bacterial infections through the discovery and development of innovative broad-spectrum antibiotics, announced today the presentation of research on aminoglycoside (AG) resistance trends and comparative AG toxicities at the 19th Annual European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), being held May 16-19, 2009 in Helsinki, Finland.

In three separate sessions, Achaogen and its research collaborators, including the Jones Microbiology Institute Laboratories in Iowa and Paul M. Tulkens, M.D. of the Université catholique de Louvaine, Belgium, are highlighting study results that underscore the critical need for well-tolerated, next-generation AGs to combat multi-drug resistant Gram-negative pathogens and address a growing public health concern. AGs have been part of the clinical infectious disease armamentarium for roughly half a century; however, as the Achaogen and JMI Laboratories research shows, rates of bacterial resistance to existing AGs, including such widely used agents as gentamicin and amikacin, are far higher in all parts of the world than was expected, suggesting a need for a next-generation AGs that can treat these resistant pathogens.

“The data being presented at ECCMID demonstrate that global resistance to AGs is increasing more rapidly than previously thought, and shows that resistance mechanisms of various Gram-negative pathogens are limiting the utility of other currently marketed antibiotics across most, and possibly all known drug classes,” stated Kevin Judice, Ph.D., chief executive officer and chief scientific officer of Achaogen. “Bacteria are constantly evolving and becoming more resistant, and these findings reinforce the urgent need for new therapies to combat these varied mechanisms of resistance.”

Achaogen's novel aminoglycoside agents—*neoglycosides*—have shown broad-spectrum efficacy *in vitro* and *in vivo* against a wide range of multi-drug resistant Gram-negative organisms (including *E. coli*, *K. Pneumoniae*, *P. aeruginosa*, and *Enterobacter* spp.), as well as multi-drug resistant Gram-positive bacteria (including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Staphylococcus* (VRSA). They also overcome known aminoglycoside resistance mechanisms. Achaogen's most advanced neoglycoside, ACHN-490, is being studied in a Phase 1 trial and initial clinical data are expected later this year.

Overview of Findings

“Ten-year trend in aminoglycoside resistance from a worldwide collection of Gram-negative pathogens” (Saturday, May 16); Poster # 636

The study assessed resistance trends to aminoglycosides over a ten-year period, using a global sample of Gram-negative pathogens. This study determined the resistance rates of commonly prescribed AGs (gentamicin, tobramycin, amikacin) against over 20,000 bacterial strains from nine Gram-negative bacterial species gathered from medical centers around the world. In particular, resistance to AGs from *E. coli*, the most common Gram-negative pathogen isolated in the study, increased in all geographic regions. Notably, in regions outside of North America, more than 50% of *Acinetobacter* spp. and more than 20% of *P. aeruginosa* isolates collected during 1998-2007 were resistant to gentamicin. The highest rates of AG resistance were observed in the Latin America and Asia-Pacific regions. The study results underscore the global issue of bacterial resistance to available AGs, and the value of developing new therapies, such as Achaogen's neoglycosides, to treat multi-drug resistant Gram-negative infections.

“Surveying aminoglycoside resistance mechanisms: a tool for the development of neoglycosides” (Saturday, May 16); Poster #643

Surveying AG resistance mechanisms among selected clinical isolates allows researchers to determine the spectrum of activity required of new compounds to overcome bacterial resistance to existing agents. In this study, multi-drug resistance was defined by resistance to three drug classes: aminoglycosides, fluoroquinolones and cephalosporins. The results demonstrate that while the overall prevalence of resistance to AGs is increasing, the distribution of AG-resistant mechanisms amongst AG-resistant isolates worldwide has remained stable during the past 20 years, suggesting that new agents that evade these mechanisms, such as neoglycosides, should remain useful for a long period of time against today's AG-resistant bacteria.

In addition, a poster entitled *“Quantitative comparison of aminoglycosides nephrotoxicity in rats for effective screening and evaluation of new derivatives, and dosing rationales that minimize toxicity,”* Poster #1979, will be presented on Tuesday, May 19 at the ECCMID. This poster reviews data from a newly refined rat toxicity model that effectively quantifies the comparative nephrotoxicity of various aminoglycosides. This model allows for effective preclinical screening

of Achaogen's neoglycosides, and has informed the company's selection of optimal dosing for clinical studies.

About ACHN-490

Achaogen's novel aminoglycoside agents—neoglycosides—overcome known aminoglycoside resistance mechanisms. Leveraging modern chemistry and biology, as well as the extensive scientific and clinical knowledge gained from decades of aminoglycoside usage, Achaogen is poised to enhance the prominence and utility of this important class of antibacterials against 21st-century pathogens.

Achaogen's lead neoglycoside, ACHN-490, has displayed efficacy in research and nonclinical studies against systemic infections caused by multi-drug resistant (MDR) Gram-negative bacteria (*e.g.*, *E. coli*, *K. pneumoniae*, and *P. aeruginosa*) and MRSA. The company initiated a Phase 1 clinical trial in early 2009 and data from this trial are expected in the second half of 2009.

About Achaogen

Achaogen is a clinical stage biopharmaceutical company focused on the discovery and development of innovative, broad-spectrum antibiotics to treat multi-drug resistant bacterial infections. Resistance to available antibacterial therapies continues to rise at an alarming rate, and Achaogen is poised to meet the evolving needs of this market by applying its anticipatory science, developing drugs today that will combat tomorrow's resistant pathogens. This scientific strategy represents a novel approach to addressing the global bacterial resistance crisis.

South San Francisco-based Achaogen is backed by top-tier venture investors and has received substantial non-dilutive funding from NIH, the U.S. Department of Defense, the Wellcome Trust and other sources. Venture capital investors include 5 AM Ventures, ARCH Venture Partners and Domain Associates, Venrock Associates and Versant Ventures. For more information, please visit the company's website at www.achaogen.com.

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