

# **NEWS RELEASE**

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## Achaogen Announces ACHN-490 Clinical Data at the 49th Annual ICAAC Meeting

-Achaogen's Neoglycoside Shown to be Well-Tolerated in Phase 1, Dose-Ranging Clinical Trial-

-Additional Preclinical Data Validates ACHN-490's Consistent Activity Against Gram-Negative and Aminoglycoside-Resistant Bacteria-

SAN FRANCISCO, CA, September 14, 2009 – 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, today announced the results of a Phase 1 trial and preclinical data on its lead drug candidate ACHN-490 at the 49<sup>th</sup> Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) Annual Meeting in San Francisco, CA. ACHN-490 has shown preclinical activity against multi-drug resistant (MDR) Gram-negative and Gram-positive pathogens, and is the most advanced drug in Achaogen's next-generation aminoglycosides, or neoglycosides.

"We are very pleased with the safety data observed in this Phase 1 clinical trial of ACHN-490," said Kevin Judice, Ph.D., chief executive officer and chief scientific officer of Achaogen. "The clinical safety data combined with the powerful preclinical efficacy data reinforces ACHN-490's potential as a novel treatment for multi-drug resistant bacterial infections. We will continue to explore the clinical utility of ACHN-490 in Phase 2 trials, expected to commence in early 2010."

The Phase 1 trial explored the safety, tolerability and pharmacokinetics (PK) of ACHN-490 in escalating single dose (SD) and once-daily multiple doses (MD) at five different dose levels in a randomized, double blind, placebo-controlled design. Thirty-two subjects were evaluated in four arms of eight subjects per arm (6 active, 2 placebo). There was no evidence of any treatment-

related effects on renal, cochlear or vestibular function. Results support the further study of ACHN-490 in high-dose, once-daily, short course therapy in patients with serious infections.

Achaogen also presented additional preclinical data of ACHN-490 in eight posters at ICAAC. Key findings included:

- ACHN-490 is metabolically stable and its PK profile supports use of high doses in short infusions, administered once-daily to achieve high Cmax and AUC, which are important for safety and efficacy.
- ACHN-490 demonstrated a potent, rapid, bactericidal effect for strains harboring known resistance mechanisms to widely-used aminoglycosides.
- ACHN-490 demonstrated consistent activity against leading Gram-negative pathogens, including those with increasingly prevalent resistance mechanisms to other classes of antimicrobial agents.
- ACHN-490 showed promise as a novel agent against Enterobacteriaceae, including multi-drug resistant KPC+ strains.
- ACHN-490 is active against pathogens that are the leading causes of complicated urinary tract infections (cUTI), even in the presence of mechanisms causing resistance to current front-line antimicrobial agents.

The ACHN-490 Phase 1 and preclinical data abstracts and posters presented at ICAAC are available online through Achaogen's website at <a href="www.achaogen.com">www.achaogen.com</a>.

"The exciting thing about the preclinical and clinical data on ACHN-490 presented at ICAAC is the translatability of the preclinical efficacy data into humans, combined with the positive safety profile observed in healthy volunteers," stated Joseph S. Solomkin, M.D., professor of surgery at the University of Cincinnati. "With antibiotic drug development, the results we see in animal models tend to be more predictive of human experience because the microbials or bugs are the same – only the host is different. With that in mind, these data are very promising for ACHN-490 as an emerging weapon in the fight against multi-drug resistant bacteria."

### **About ACHN-490**

Achaogen's novel aminoglycoside agents—neoglycosides—overcome known aminoglycoside resistance mechanisms as well as resistance mechanisms that thwart other well-known classes of antibiotics. 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. Achaogen recently completed a Phase 1 randomized, double blind, placebo-controlled trial assessing the safety, tolerability and pharmacokinetics in escalating single (SD) and once-daily multiple (MD) doses up to five doses of ACHN-490. Achaogen plans to initiate a Phase 2 clinical trial of ACHN-490 in patients with complicated urinary tract infections (cUTI) in early 2010.

### **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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