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# Achaogen Announces First Patient Enrollment in a Phase 3 Clinical Trial of Plazomicin to Treat Infections Caused by Carbapenem-Resistant Enterobacteriaceae (CRE)

**South San Francisco, CA, September 17, 2014** – Achaogen, Inc. (NASDAQ: AKAO), a clinical-stage biopharmaceutical company developing novel antibacterials to treat multi-drug resistant (MDR) gram-negative infections, announced today that the first patient has been enrolled in a Phase 3 clinical trial of plazomicin to treat infections caused by carbapenem-resistant Enterobacteriaceae (CRE).

The Phase 3 clinical trial is designed to demonstrate the superiority, in terms of mortality at 28 days, of a plazomicin-based regimen compared with a colistin-based regimen in the treatment of patients with bloodstream infections or nosocomial pneumonia due to CRE. As previously reported by Achaogen, the trial is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration. Achaogen's plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority (BARDA) for up to $103.8 million.

"Commencing enrollment into this Phase 3 clinical trial of plazomicin is a significant accomplishment as hospital based CRE infections pose a serious health threat globally," said Kenneth J. Hillan, Chief Executive Officer of Achaogen. "We have initiated sites in the U.S. and Europe, and will further expand to sites in other important geographic regions in the coming months. The clinical advancement of plazomicin moves Achaogen closer to reaching our goal of providing effective new treatments to patients with life threatening gram-negative infections, such as CRE."

The need for new antibiotics to treat CRE is particularly acute, as these bacteria are commonly multi-drug resistant—that is, they are insensitive to nearly all antibiotics commonly used to treat gram-negative infections, including carbapenems, cephalosporins, beta-lactam/beta-lactamase inhibitor combinations, fluoroquinolones, and currently-marketed aminoglycosides. Resistance to carbapenems has been highlighted as a particular concern because carbapenems are one of the last lines of defense against antibiotic-resistant gram-negative infections. Most CRE express enzymes called carbapenemases, which break down the carbapenem antibiotic molecule before it can kill the bacteria. Due to the lack of effective therapies, CRE infections are associated with significant mortality, with up to 50% mortality observed in patients with bloodstream infections.

Details regarding the plazomicin Phase 3 clinical trial can be viewed at ClinicalTrials.gov: http://www.clinicaltrials.gov/ct2/show/NCT01970371.

**About Plazomicin**

Plazomicin is a novel aminoglycoside antibiotic that Achaogen designed to overcome clinically relevant aminoglycoside resistance mechanisms. It has shown potent bactericidal activity in nonclinical studies against important gram-negative pathogens, including CRE. Plazomicin is also being developed for the treatment of infections caused by certain biothreat agents, including *Yersinia pestis* and *Francisella tularensis*, which respectively cause plague and tularemia. The development of plazomicin is supported in part by the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services.

**About Achaogen**

Achaogen is a clinical-stage biopharmaceutical company passionately committed to the discovery,

development, and commercialization of novel antibacterials to treat MDR gram-negative infections. Achaogen is developing plazomicin, its lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including CRE. Through the Special Protocol Assessment procedure, the U.S. Food and Drug Administration has agreed that the design and planned analyses of Achaogen's single pivotal Phase 3 trial adequately address objectives in support of a New Drug Application. Achaogen's plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority. Plazomicin is the first clinical candidate from Achaogen's gram-negative antibiotic discovery engine, and Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections. Achaogen's common stock is listed on The NASDAQ Global Market under the ticker symbol "AKAO." Additional information can be found at the company's website: www.achaogen.com.

**Forward-Looking Statements**

*To the extent that statements contained in this press release are not descriptions of historical facts regarding Achaogen, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including Achaogen's expectations regarding the success of its Phase 3 trial for plazomicin, its ability to enroll additional patients in such trial, its ability to initiate additional trial sites, its ability to provide effective new treatments to patients with life threatening gram-negative infections, its ability to develop plazomicin as a treatment for infections caused by biothreat agents, and its ability to discover, develop and commercialize novel antibacterials to treat MDR gram-negative infections. Such forward-looking statements involve substantial risks and uncertainties that could cause Achaogen's development program, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the preclinical and clinical development process; specific risks related to the Phase 3 trial of plazomicin, including the lack of a prior clinical trial in patients with CRE infections and challenges in enrolling an adequate number of patients with rare infections; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of commercialization and gaining market acceptance; the risk that bacteria may evolve resistance to plazomicin; the risk of failure to successfully validate, develop and obtain regulatory clearance or approval for Achaogen's in vitro assay for plazomicin; Achaogen's dependence on ARK Diagnostics, Inc. to develop and manufacture Achaogen's in vitro assay for plazomicin; risks and uncertainties as to Achaogen's ability to raise additional capital to support the development of plazomicin and its other programs; uncertainties regarding the availability of adequate third-party coverage and reimbursement for newly approved products; Achaogen's reliance on third parties to conduct certain preclinical studies and all of its clinical trials; Achaogen's reliance on third-party contract manufacturing organizations to manufacture and supply its product candidates and certain raw materials used in the production thereof; Achaogen's dependence on its Chief Executive Officer; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that BARDA could terminate Achaogen's contract for the funding of the plazomicin development program; risk of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Achaogen's patents or proprietary rights; and the risk that Achaogen's proprietary rights may be insufficient to protect its technologies and product candidates. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Achaogen's business in general, see Achaogen's Form 10-Q for the fiscal quarter ended June 30, 2014, filed with the Securities and Exchange Commission on August 11, 2014. Except as required by applicable law,*

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*Achaogen does not undertake to publicly update or revise any forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances or otherwise.*

**Contact**

Candice Knoll
Blueprint Life Science Group

415.375.3340 Ext. 105

cknoll@bplifescience.com