ACHAOGEN

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# Achaogen Announces Agreement with FDA on a Special Protocol Assessment for a Phase 3 Clinical Trial of Plazomicin to Treat Infections Caused by Carbapenem-Resistant Enterobacteriaceae (CRE)

**South San Francisco, CA, September 23, 2013** – Achaogen, Inc. announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for a Phase 3 clinical trial of plazomicin in patients with serious multi-drug resistant (MDR) gram-negative bacterial infections. SPA agreement from the FDA indicates that the design and planned analyses of the clinical trial address objectives necessary to support a new drug application (NDA). This Phase 3 trial is designed as a superiority study to evaluate the efficacy and safety of plazomicin compared with colistin in patients with bloodstream infections and nosocomial pneumonia caused by CRE.

“Reaching agreement with the FDA on the plazomicin Phase 3 study design is a significant milestone for Achaogen as well as a meaningful step forward in antibiotic drug development for new regulatory pathways that address serious unmet medical needs,” said Kenneth Hillan, M.B. Ch.B, Chief Executive Officer and Chief Medical Officer for Achaogen. “FDA agreement on this protocol provides a clear path for a streamlined development plan for plazomicin. The trial is expected to start in fourth quarter, 2013.”

CRE are a global and growing public health concern. These bacteria are resistant to nearly all available antibiotics, including carbapenems, one of the last lines of defense against resistant infections. Mortality rates approach 50% in CRE patients with bloodstream infections, and the U.S. Centers for Disease Control and Prevention has categorized CRE as an “urgent” public health threat requiring immediate and aggressive action.

Plazomicin is a next-generation aminoglycoside antibiotic that Achaogen engineered to overcome key aminoglycoside resistance mechanisms. It has potent bactericidal activity 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 cause plague and tularemia, respectively). The development of plazomicin is supported 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 biopharmaceutical company dedicated to discovering, developing, and commercializing treatments for serious infections caused by MDR gram-negative bacteria. In addition to its lead asset plazomicin, the company has active research and early development programs focused on novel mechanisms targeting gram-negative bacteria. Achaogen has established and advanced its specialized research and development capabilities using a blend of funding from private investors and partnerships with governmental entities, including BARDA, the National Institute of Allergy and Infectious Diseases, and the U.S. Department of Defense. For more information, please visit the company’s website at www.achaogen.com.

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