ACHAOGEN

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Achaogen Announces Enrollment of First Patient in EPIC, a Phase 3 Clinical Trial for the Treatment of Complicated Urinary Tract Infections (cUTI) With Plazomicin

Achaogen Also Announces First Patients Enrolled in Cohort 2 of the CARE Trial for the Treatment of Infections Due to CRE With Plazomicin

SOUTH SAN FRANCISCO, Calif., Jan. 11, 2016 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a clinical-stage biopharmaceutical company developing novel antibacterials addressing multi-drug resistant (MDR) gram-negative infections, announced today the enrollment of its first patient in EPIC (**E**valuating **p**lazomicin **i**n **c**UTI), a Phase 3 clinical trial of plazomicin to treat complicated urinary tract infections (cUTI) including acute pyelonephritis (AP). Achaogen also announced today the enrollment of patients in the second cohort of its Phase 3 CARE (**C**ombating **A**ntibiotic **R**esistant **E**nterobacteriaceae) study, including a patient enrolled with cUTI caused by carbapenem-resistant Enterobacteriaceae (CRE).

EPIC is a multi-national, randomized, controlled, double-blind study which is expected to create a substantial opportunity for plazomicin to address the unmet medical need arising from multi-drug resistant (MDR) infections of the urinary tract. EPIC is intended to serve as a single pivotal trial supporting a new drug application (NDA) for plazomicin in the United States. The Company remains on track to release top-line results from EPIC and submit an NDA in the second half of 2017.

"MDR gram-negative infections are a significant and increasing problem. We need new antimicrobials for treatment as the current armamentarium is sparse and/or toxic," said Ravi Kamepalli, MD, Regional Infectious Diseases and Infusion Center (RIDIC) in Lima, OH. "The EPIC trial will enable us to assess plazomicin's efficacy and safety in patients with complicated UTI and evaluate its potential to significantly advance the field."

The CARE study, initiated in 2014, is a Phase 3 randomized controlled study of plazomicin in the treatment of patients with bloodstream infections (BSI) or pneumonia due to carbapenem-resistant Enterobacteriaceae (CRE). A second protocol amendment (AM2) added a second single-arm cohort (Cohort 2) to the trial enabling enrollment of patients with confirmed CRE who are not eligible for the randomized study arms (Cohort 1). The Company expects Cohort 2 will generate important additional clinical data for plazomicin in the treatment of a wide range of patients with CRE infections, including cUTI, a patient population representing a significant unmet medical need.

"Enrolling the first patients into EPIC and CARE Cohort 2 is an exciting milestone in our development program for plazomicin," said Kenneth Hillan, Achaogen's Chief Executive Officer. "The EPIC study is an integral part of our strategy to expedite the path to market for plazomicin, and Cohort 2 of the CARE study is reflective of our ongoing commitment to generate important clinical data for plazomicin in the treatment of patients with CRE infections who are desperately in need of new therapeutic options."

About Plazomicin
Plazomicin is a novel aminoglycoside antibiotic that Achaogen engineered to overcome key aminoglycoside resistance mechanisms. It is being developed for the treatment of bacterial infections due to Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae, or CRE. Plazomicin remains active against most MDR Enterobacteriaceae, including CRE, where most other antibiotics, have limited potency due to resistance. 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 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, Achaogen's lead product candidate, for the treatment of serious urinary tract, lung, and bloodstream infections due to Enterobacteriaceae, including CRE. 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. For more information, please visit www.achaogen.com.

Forward-Looking Statements
This press release contains forward looking statements. All statements other than statements of historical facts contained herein 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 (i) the potential for Achaogen's Phase 3 EPIC trial to create a substantial opportunity for plazomicin to address the unmet medical need arising from MDR infections of the urinary tract; (ii) the ability for Achaogen's Phase 3 EPIC trial to serve as a single pivotal trial supporting an NDA for plazomicin; (iii) the timing of release of EPIC's top-line results and Achaogen's submission of an NDA in the second half of 2017; (iv) whether the EPIC trial will enable Achaogen to assess plazomicin's efficacy and safety in patients with cUTI and evaluate plazomicin's potential to significantly advance the field. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause Achaogen's actual results, performance or achievements to be materially different from any future results, performance or achievements 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 ongoing Phase 3 EPIC trial; the risk of failure to successfully validate, develop and obtain regulatory clearance or approval for the in vitro diagnostic (IVD) assay for plazomicin; the risks and uncertainties of the regulatory approval process; the risk that bacteria may evolve resistance to plazomicin; Achaogen's dependence on ARK Diagnostics, Inc. to develop and manufacture the IVD 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 President and Chief Executive Officer; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that the Biomedical Advanced Research and Development Authority 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 current and future reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015 and its Annual Report on Form 10-K for the fiscal year ended December 31, 2014. Achaogen does not plan 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.

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